Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members were for the period of 2019 to 2020:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator Dr.Kailash wagh- Professor. (Microbiology)

Research associates: Dr.– Suyog chopde Professor (Pharmacology)

Dr. Nilesh Bendale- Professor (PSM)

Mr. Prashanth Kumar Guddeti -Asst. Professor-

Mr.Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)

and HOD Anatomy,HOD Physiology and HOD, Biochemistry
HOD, Pharmacology HOD, Microbiology
HOD, Pathology
HOD, FMT
HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(**Note**-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Priyanka Mr.ritesh and Mr .Bhushan

JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members were for the period of 2015 to 2018:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator - Dr. Nagendra A.N. Professor & HOD Microbiology

Research associates: - Dr. Kailash wagh – associate Professor, Microbiology

Dr.KamaleshVishvkarma–assistant Professor, (2018-2019)

Dr. Nilesh Bendale- Professor (PSM)

Mr.Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)
and HOD Anatomy
HOD Physiology
HOD, Biochemistry
HOD, Pharmacology
HOD, Microbiology
HOD, Pathology
HOD, FMT
HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(**Note**-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Priyanka Mr.ritesh and Mr .Bhushan

Dean
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members are posted for various post for the period of 2021:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator - Dr.Jayant Deshmukh - Professor. (Microbiology)

Research associates: - Mr. Prashanth Kumar Guddeti - Asst. Professor-

Dr. Suyog chopde –Professor (Pharmacology)

Dr. Nilesh Bendale- Professor (PSM)

Mr.Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)

and HOD Anatomy, HOD Physiology and HOD, Biochemistry HOD, Pharmacology,HOD, Microbiology HOD, Pathology HOD, FMT

HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(**Note**-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Nagama Mr.Ahmad and Mr. Nayeem

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

CRL EQUIPMENT LIST

Anatomy

Anthropometer Set, spreading callipers, Goniometer

Physiology

Brodies's extension kymograph and artificial res.pump, perimeter, PFT Machine, Diabetes Risk profiler 16 channel polygraph machine, 32 channel EEG, Sherrington Starling kymograph (electrically driven), Gas analyzer automatic for CO2, O2, N2

Biochemistry

PH Meter, HPLC, Spectrophotometer (200-1000nm), Chemical analytical balance, Electromagnetic stirrer, Distillation water plant, UV-transilluminators,

Pharmacology

1) Digital photoactometer, Magnetic stir hot plate, Manikins for demonstration of intravenous injection, Analgesiometer, Digital spectrophotometer, convulsiometer, Cook's pole climbing response apparatus

Pathology Manual Rotary Microtome,

Forensic medicine

1) Weighing Machine For Organs, Weighing Machine For Fetus, Dissection Set Complete, Brain Knife, Hack Saw

Community medicine

1) Chloroscope, Horrock's Apparatus, Haemoglobinometer, BP Apparatus (Digital), Stethoscope Sound level meter, Harpender Calipers (for skinfold thickness)

Medicine

1) BLS and Airways mannequins (child and adult). – skill lab, ECG Machine, Laryngoscope

Surgery 1) Suturing mannequin- skill lab

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

GF/DUPMC/D.O/ 2021/CRL 02 **Date: 4/06/2021**

A Meeting of newly reformed central research laboratory is scheduled on 8/06/2021.

Time: 11.00 to 11.45 AM

Venue: Dean Office.

All research associates members/ Acting HOD/ concern representative are requested to attend the meeting.

Agenda-

1. Introduction to central research laboratory as per new rule of NMC.
2. Finalise Training schedule for concern technicians.

Please be present with concern documents

Chairman
CRL, DUPMC

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members were for the period of 2015 to 2018:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator Dr. Nagendra A.N. HOD Microbiology

Research associates: Dr. Rahul Prakash Bhavasar–Professor (Pharmacology)

Dr. Nilesh Bendale- Professor (PSM)

Mr. Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)
and HOD Anatomy
HOD Physiology
HOD, Biochemistry
HOD, Pharmacology
HOD, Microbiology
HOD, Pathology
HOD, FMT
HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(Note-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Priyanka Mr.ritesh and Mr .Bhushan

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members were for the period of 2018 to 2020:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator Dr.Kailash wagh- Professor. (Microbiology)

Mr. Prashanth Kumar Guddeti - Asst. Professor- (Microbiology)

Research associates: Dr. Rahul Prakash Bhavasar–Professor (Pharmacology)

Dr. Nilesh Bendale- Professor (PSM)

Mr.Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)
and HOD Anatomy
HOD Physiology
HOD, Biochemistry
HOD, Pharmacology
HOD, Microbiology
HOD, Pathology
HOD, FMT
HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(Note-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Priyanka Mr.ritesh and Mr .Bhushan

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, JalgaonKh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

- **The central research laboratory consists of the following members are posted for various post for the period of 2021:**

Chairperson -Dean - Dr. N.S.Arvikar

Co-Ordinator Dr.Jayant Deshmukh - Professor. (Microbiology)

Mr. Prashanth Kumar Guddeti - Asst. Professor- (Microbiology)

Research associates: Dr. Rahul Prakash Bhavasar–Professor (Pharmacology)

Dr. Nilesh Bendale- Professor (PSM)

Mr.Vijay More –Statistician

Members: Dr. Chandraya kante , Medical Superintendent (DUPMC& H)
and HOD Anatomy
HOD Physiology
HOD, Biochemistry
HOD, Pharmacology
HOD, Microbiology
HOD, Pathology
HOD, FMT
HOD of Dept. Of General Medicine
HOD Dept. Of Paediatrics
HOD Dept. Of TB Chest
HOD Dept. Of Skin VD
HOD Psychaitry
HOD Dept. Of General Surgery
HOD Dept. Of Orthopedics
HOD Dept. Of ENT
HOD Dept. Of Opthalmology
HOD Dept. Of OBGY
HOD Dept. Of Anaesthesia
HOD Dept. Of Radiology
HOD Dept. Of Community medicine

(Note-staff from various departments is involved as per the requirement and type of project.)

Clerk: Mr.Arvind chaudhari

Lab Technician: Miss Nagama Mr.Ahmad and Mr .Nayeem

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To promote interest and aptitude for research among medical undergraduates.

ii) To give an idea to the students for getting opportunities to participate in ICMR projects.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Nagendra

Dr .Nagendra A.N

Co-ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2016/ Minutes of Meeting **DATE: 15/02/2016**

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr.Ranjeet patil	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr.Janakram deshmukh	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Vijaya Mali	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr. Sunaina Anandkumar Malik	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To promote interest and aptitude among medical undergraduates in Basic research methodology.

ii) To give an idea to the medical undergraduates how to choose research topic for their field of interest.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr .Nagendra A.N

Co-ordinator

CRL.DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2016/ **Minutes of Meeting**

DATE: 18/08/2016

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr.Ranjeet patil	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr.Janakram deshmukh	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Vijaya Mali	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr. Sunaina Anandkumar Malik	Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To organize departmental level lecture to delivered various way to find out research topic through internet.

ii) To acquainted visit programme of medical undergraduates to CRL

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr .Nagendra A.N

Co-Ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2016/ Minutes of Meeting

DATE: 15/05/2017

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr. Atul Bhagwanrao Agte	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Sunil Vasudeo Chaudhari	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr Ragini Rajesh Patil	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding research topic through library visit.

ii) To make awareness to medical undergraduate how to assess journals and books for their research topic

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Nagendra

Dr .Nagendra A.N

Co-Ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2017/ **Minutes of Meeting**

DATE: 27/10/2017

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr. Atul Bhagwanrao Agte	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Sunil Vasudeo Chaudhari	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr Ragini Rajesh Patil	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding research topic concern with their selection.
   a) The focus should be given to research rather than just the collection of data
   b) Using retrospective study and prospective study
   c) Fascinating Medical Topics Related To Health
   d) Medical Research Topics That Create Controversy-should be exclude.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr .Nagendra A.N

Co-Ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2018/ **Minutes of Meeting**

DATE: 04/06/2018

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr. Atul Bhagwanrao Agte	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Sunil Vasudeo Chaudhari	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Narayan Arvikar	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr Ragini Rajesh Patil	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding research topic and submission of manuscript.

a) Duplicate or redundant submission is the same manuscript (or the same data) that is submitted to different journals at the same time. This violates international copyright laws, ethical conduct, and cost effective use of resources.

b) Submitted manuscripts should not have been published or currently submitted elsewhere. Duplicate publication is a violation of the code of research ethics.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Nagendra

Dr .Nagendra A.N

Co-Ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2018/ Minutes of Meeting

DATE: 03/11/2018

Location: Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr Shashank Sudhakar Jadhav	H.O.D of Physiology	
9.	Dr. Atul Bhagwanrao Agte	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Sunil Vasudeo Chaudhari	HOD of Dept. Of General Medicine	
14	Dr.Jeevan Kulkarni	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Dwarkadas Tapadiya	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Narayan Arvikar	HOD Dept. Of OBGY	
22	Dr.Jayant Deshmukh	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Harikisan Bridchandji Rathi	HOD Dept. Of Community medicine	
25	Dr Ragini Rajesh Patil	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding research topic and updating of their research topic.
ii) Find out new current practices concern with their topic.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.
4. Discussion about above mention agenda.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr. Kailash wagh

Co-Ordinator

DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2019/ Minutes of Meeting

DATE: 13/02/2019

Location:
Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr. Shivanand Shriram Rathod	H.O.D of Physiology	
9.	Dr. Anand Pandurang Thorat	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Dinesh Eknath Nehete	HOD of Dept. Of General Medicine	
14	Dr.Anant Ganpat Bendale	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr. Rajendra Iccharam Sarode	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Abhinay Harankhedkar	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Ashok Parshuram Kale	HOD Dept. Of Community medicine	
25	Dr Kiran Martand Bhirud	HOD Dept Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding research topic and biosafety precautions in laboratory

ii) To train them how to take universal precautions.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.
4. Discussion about above mention agenda.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr. Kailash wagh

Co-Ordinator

CRL. DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2019/ Minutes of Meeting

DATE: 3/11/2019
Location:
Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Nagendra A.	Co-ordinator	
4.	Dr. Kailash wagh	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr. Shivanand Shriram Rathod	H.O.D of Physiology	
9.	Dr. Anand Pandurang Thorat	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Vilas Mahadeorao Sangole	H.O.D, of Pathology	
12	Dr. Jayant Ramakant Shinde	H.O.D, of FMT	
13	Dr. Dinesh Eknath Nehete	HOD of Dept. Of General Medicine	
14	Dr.Anant Ganpat Bendale	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr. Rajendra Iccharam Sarode	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr. Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Abhinay Harankhedkar	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Ashok Parshuram Kale	HOD Dept. Of Community medicine	
25	Dr Kiran Martand Bhirud	HOD Dept Ophthalmology	Kiran

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase awareness of medical undergraduate regarding about their research topic ethics committee approval rule and regulations.

ii) To teach them process of submission of their thesis and provide no duce of their instruments used by them.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.
4. Discussion about above mention agenda.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr. Kailash wagh

Co-Ordinator

CRL.DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2020/ Minutes of Meeting

DATE: 05/10/2020

Location:
Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Kailash wagh	Co-Ordinator	
4.	Dr.Prashant	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr. Shivanand Shriram Rathod	H.O.D of Physiology	
9.	Dr. Anand Pandurang Thorat	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Anagha Pandurang Amale	H.O.D, of Pathology	
12	Dr. Jayant Shinde	H.O.D, of FMT	
13	Dr.Dinesh Eknath Nehete	HOD of Dept. Of General Medicine	
14	Dr.Anant Ganpat Bendale	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Rajendra Iccharam Sarode	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr.Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Abhinay Ramchandra Harankhedkar	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Dilip Narayan Dhekale	HOD Dept. Of Community medicine	
25	Dr. Kiran Martand Bhirud	Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase instrument capacity of laboratory
ii) More importance given to purchase of molecular level machines.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.
4. Discussion about above mention agenda.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr. Kailash wagh

Co-Ordinator

CRL.DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2020/ **Minutes of Meeting**

DATE: 22/09/2020
Location:
Dean's Office
Recorded By: Dr.Wagh K.B

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Kailash wagh	Co-Ordinator	
4.	Dr.Prashant	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr. Shivanand Shriram Rathod	H.O.D of Physiology	
9.	Dr. Anand Pandurang Thorat	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Anagha Pandurang Amale	H.O.D, of Pathology	
12	Dr. Jayant Shinde	H.O.D, of FMT	
13	Dr.Dinesh Eknath Nehete	HOD of Dept. Of General Medicine	
14	Dr.Anant Ganpat Bendale	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Rajendra Iccharam Sarode	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr.Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Abhinay Ramchandra Harankhedkar	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Dilip Narayan Dhekale	HOD Dept. Of Community medicine	
25	Dr. Kiran Martand Bhirud	Ophthalmology	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To increase research activity in CRL

ii) To take follow up concern with internal Quality control.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for CRL, DUPMCH are discussed.
4. Discussion about above mention agenda.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr. Jayant Deshmukh
Co-Ordinator
CRL.DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

CENTRAL REASERACH LABORATORY COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

CRL/ 2021/ Minutes of Meeting **DATE: 26/10/2021**

Location: Dean's Office

Recorded By: Dr.Prashant

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. N.S.Arvikar	Chairman	
2.	Dr. Chandraya kante	Medical Superintendent	
3.	Dr. Jayant M. Deshmukh	Co-Ordinator	
4.	Dr.Prashant	Research associates	
5.	Dr. Nilesh Bendale	Research associates	
6.	Mr.Vijay More	Statistician	
7.	Dr Amrut Mahajan	H.O.D of Anatomy	
8.	Dr. Shivanand Shriram Rathod	H.O.D of Physiology	
9.	Dr. Anand Pandurang Thorat	H.O.D, of Biochemistry	
10.	Dr. Devendra Ramesh Chaudhari	H.O.D, of Pharmacology	
11.	Dr. Anagha Pandurang Amale	H.O.D, of Pathology	
12	Dr. Jayant Shinde	H.O.D, of FMT	
13	Dr.Dinesh Eknath Nehete	HOD of Dept. Of General Medicine	
14	Dr.Anant Ganpat Bendale	HOD Dept. Of Paediatrics	
15	Dr. Deepak Patil	HOD Dept. Of TB Chest	
16	Dr.Nilesh Bhirud	HOD Dept. Of Skin VD	
17	Dr. Mayur Muthe	HOD Psychaitry	
18	Dr.Shivaji Sadulwad	HOD Dept. Of General Surgery	
19	Dr.Rajendra Iccharam Sarode	HOD Dept. Of Orthopedics	
20	Dr.Bhalchandra Paike	HOD Dept. Of ENT	
21	Dr.Maya Arvikar	HOD Dept. Of OBGY	
22	Dr.Abhinay Ramchandra Harankhedkar	HOD Dept. Of Anaesthesia	
23	Dr. Kiran Patil	HOD Dept. Of Radiology	
24	Dr. Dilip Narayan Dhekale	HOD Dept. Of Community medicine	
25	Dr. Kiran Martand Bhirud	Ophthalmology	

	GODAVARI FOUNDATION'S DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGOAN KH. Central Research Laboratory	
CCLM/SOP No./Version:01/02	Subject: CRL Function: Review: 1 Year	Laboratory SOP Date of creation: 08/06/2021
Location: CRL	No. of Copies: 02	Pages : 02

Location: About 500sqmeter areas on 2nd Floor, Near Museum, college premise.

Scope of research work: Major Research works from all departments separately or in integrated way.

Purpose:

1) To provide most recent research methodologies in an integrated way to the faculty members of all departments for carrying out novel research works in medical science.
2) Institution encourages students to participate in research and ICMR Projects.
3) As part of the curriculum, the PG students participate in research through their dissertation, UG students through project work and Faculty continue Research in area of their work.

Administrative control:Central Research Laboratory Committee

Chairman: Dr. Arvikar N.S., Dean

Coordinator: Dr.Jayant Deshmukh- Professor. (Microbiology)
Mr. Prashanth Kumar Guddeti - Asst. Professor- (Microbiology)

Research associates: Dr. Rahul Prakash Bhavasar–Ass.Professor (Pharmacology)
Dr. Nilesh Bendale- Professor (PSM)
Mr.Vijay More –Statistician

Members: Dr. Chandrayakante,Medical Superintendent (DUPMC& H)and
HOD Anatomy
HOD Physiology
HOD, Biochemistry
HOD, Pharmacology

	Name	Signature	Date
Prepared by:	Dr. Prashant kumar Guddeti		08/06/2021
Approved by:	Dr. Arvikar N.S.		08/06/2021

HOD, Microbiology

HOD, Pathology

HOD, FMT

HOD of all 3 rd year subjects

(Note-staff from various departments is involved as per the requirement and type of project.)

Lab Technician: Miss Nagma

Mr.Ahamad

Mr.Nayeem

Procedure

A) Selection of topic

Advances in medicine and science come from new ideas and approach developed through research. Central Research laboratory (CRL) is a facility that provides centralized research infrastructure to benefit investigators in multiple disciplines.

The CRL consists of Anatomy, Physiology, Biochemistry, Pathology, Microbiology, Pharmacology and all subjects of 3rd year MBBS. These all departments are involved as per the requirement and type of project sections to conduct research work. According of their area of interest, staff will select the topic and will submit the protocol to Co-coordinator of CRL and Ethics Committee for its approval. Researchers will start their research in central research laboratory under guidance of co-coordinator and co-investigator.

Researchers he or she must abide following steps.

1) Conflicts of Interest

At the point of submission of protocol for work, research ethics dictate that each researchers reveal any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated -

including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition.

2) Patient Consent Forms

The protection of a patient's right to privacy is essential. Please collect and keep copies of patients' consent forms on which patients or other subjects of your experiments clearly grant permission for the publication of photographs or other material that might identify them. If the consent form for your research did not specifically include this, please obtain it or remove the identifying material.

3) Ethics Committee Approval

All work dealing with original human or animal data must submit the approval letter which includes a statement on ethics approval at the beginning. This must contain the information like: the name and address of the ethics committee responsible; the protocol number that was attributed by this ethics committee; and the date of approval by the ethics committee.

In addition and as stated above, for studies conducted on human participants it must be mentioned early that written informed consent was obtained from the study participants (Similarly, for experiments involving animals researcher must state the care of animal and licensing guidelines under which the study was performed and report these in accordance with the ARRIVE (Animals in Research: Reporting In Vivo Experiments) statement. If ethics clearance was not necessary, or if there was any deviation from these standard ethical requests, please state why it was not required. Please note that the research committee may ask you to provide evidence of ethical approval. If you have approval from a National Drug Agency (or similar) please state this and provide details, this can be particularly useful when discussing the use of unlicensed drugs.

	Name	Signature	Date
Prepared by:	Dr. Prashant kumar Guddeti		08/06/2021
Approved by:	Dr. Arvikar N.S.		08/06/2021

B) Institutional committee looking after responsible conduct of research

- Institutional Ethical Committee
- Institutional Bio Safety Committee

C) Research facilities available:

1. PCR amplification- study of mutations and polymorphisms.
2. Fluorescent Microscopy -Fluorescent studies including immunofluorescence.
3. Electrophoretic unit forseparation of proteins, Detection of proteins, power pack enzymes, DNA & RNA lipids and nucleic acids,
4. HPLC- Different spectrophotometric studies.
5. Dark ground Microscopy.
6. ELISA Reader and ELISA Washer for Hormonal & Serological study.
7. Prima – 96 Thermal Cycler for Amplification, Denaturation and annealing of nucleic acid.
8. Laminar Flow Fixed Equipment for Nucleic acid separation area.
9. PCR Work Station with UV Sterilizer for Genomic study

D) Equipment'savailable in central research lab

- **Anatomy (05)**
- 1 Anthropometer Set 1
- 2 Spreading Calliper 1
- 3 Skin Calliper 1
- 4 Goniometer 1
- 5 Osteometric Board 1
- **Physiology (01)**

- 6 Perimeter 1
- Biochemistry (02)
- 7 PH Meter 1
- 8 Dabble Distillation water Plant 1
- **Pharmacology(22)**
- 9 Digital spectrophotometer 1
- 10 3 Channel Student Physiograph 1
- 11 Digital pH meter 1
- 12 Digital Rotarod Assembly Five compartment 1
- 13 Bacteriological Incubator 1
- 14 Water Bath 2
- 15 Vaccum & Pressure pump –Portable 1
- 16 Digital Disintegration test apparatus 1
- 17 Histamine Chamber 1
- 18 Super speed kymograph 1
- 19 Two bed Demineraliser 1
- 20 Auto Colorimeter 1
- 21 Cook's pole climbing response apparatus 1
- 22 Digital photo actometer 1
- 23 Analgesiometer (tail flick) 1
- 24 Vortex shaker 1
- 25 Electro Convulsiometer 1
- 27 Single unit oragan bath with kymograph 1
- 28 Centrifuge 1
- 29 Digital bench top centrifugal machine 1

	Name	Signature	Date
Prepared by:	Dr. Prashant kumar Guddeti		08/06/2021
Approved by:	Dr. Arvikar N.S.		08/06/2021

- 30 Electronic metronome 1
- 31 Carbon oxide cylinder 1
- **Pathology (01)**
- 32 Manual Rotary Microtome
- **Microbiology (17)**
- 33 Electrophoresis Complete Set 1
- 34 Elisa reader, Dispenser and washer 1
- 35 Fluorescence Microscopy 1
- 36 Incubator 1
- 37 Refrigerated Centrifuge 1
- 38 Thermostatic Water Bath 1
- 39 Serological Water Bath 1
- 40 Q.B.C. Centrifuge 1
- 41 V.D.R.L. shaker(Venereal Disease Research 1
- Laboratory)
- 42 Anaerobic Apparatus 1
- 43 Aseptic Cabinet 1
- 44 Dark ground Microscope 1
- 45 Candle jar 1
- 46 Digital PH Meter 1
- 47 Tissue Homogeniser 1
- 48 Autoclave 1
- 49 Deep freeze(-20 0 c) 1
- **Forensic Medicine (06)**
- 50 Plastic Sealer 1

	Name	Signature	Date
Prepared by:	Dr. Prashant kumar Guddeti		08/06/2021
Approved by:	Dr. Arvikar N.S.		08/06/2021

- 51 Digital Spectrophotometer 1
- 52 Tissue flotation bath 1
- 53 Slide warmer 1
- 54 Hot Plate 1
- 55 Paraffin Water Bath

	Name	Signature	Date
Prepared by:	Dr. Prashant kumar Guddeti		08/06/2021
Approved by:	Dr. Arvikar N.S.		08/06/2021

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date :19.02.2016

Circular

All teaching staff members are informed that Workshop on 'Basics of GCP' (Good Clinical Practice) is arranged for Institutional Ethics Committee (IEC) members on 25 February 2016 from 9 am to 5 pm by Dept of Pharmacology, Seth G. S. Medical College, Mumbai.

Workshop is for 25 members. Those who are interested in membership of IEC can attend the workshop.

Dean
Dr. Ulhas Patil Medical College &
Hospital, Jalgaon

Workshop on 'Basics of GCP'

At

Dr Ulhas Patil Medical Collge and hospital, Jalgaon

Conducted by

Dept of Pharmacology & Therapeutics, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012

Date: 25th February, 2016 from 9.00 am to 5.00 pm.

Program

Time	Topic	Speaker
8.00 am -9.15 am	Breakfast	
9.15 am -9.30 am	Introduction of participants	
9.30 am – 10.15 am	Overview of GCP: Principles and Practice	Dr Raakhi Tripathi* Member Secretary, Independent Ethics Committee
10.15 am -11.15 am	Ethical Guidelines: ICMR guidelines Schedule Y Indian GCP guidelines	Dr Sharmila Jalgaonkar** Member Secretary, IEC-I, Seth GSMC & KEMH.
11.15 am -11.30 am	**Tea break**	
11.30 am -12.15 pm	Investigators responsibilities	Dr Raakhi Tripathi
12.15 pm – 1.00 pm	Sponsor's responsibilities	Dr Raakhi Tripathi
1.00 pm-2.00 pm	**Lunch Break**	
2.00 pm-3.00 pm	Informed Consent Process	Dr Snehlata Gajbhiye** Member Secretary, IEC-II, Seth GSMC & KEMH.
3.00 pm-4.00 pm	Ethics Committee: Roles and responsibilities	Dr Snehlata Gajbhiye
4.00 pm-4.30 pm	Serious Adverse Event Reporting	Dr Sharmila Jalgaonkar
4.30 pm-5.00 pm	Feedback	

* Associate Professor, Department of Pharmacology & Therapeutiics, Seth GSMC & KEMH.

** Assistant Professor, Department of Pharmacology & Therapeutiics, Seth GSMC & KEMH.

Institutional Ethics Committee, DUPMCH, JALGAON

It is an independent body whose responsibility is to ensure the protection of rights, safety and well-being of human participants involved in a **clinical trial** and to provide public assurance of that protection.

The IEC will review scientific and ethical aspects of all types of **Research Studies Involving Human Participants.**

Member list

Sr. No.	Member Name	Designation
1.	Prof. Nitinchandra V. Patil	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. Narayan S. Arvikar	Member
4.	Dr. Sunil V. Chaudhari	Member
5.	Dr. (Mrs) Maya N. Arvikar	Member
6.	Dr. Rahul P. Bhavasar	Member
7.	Dr. Smita C. Pathade	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant Warke	Member
10.	Mrs. Jyotsna P. Bhirud	Member

Those who want to participate in workshop should sign below.

Sr. No	Name of Teaching Staff	Department	Signature
1	Mr. Bapurao M Bite	Pharmacology	
2.	Dr. Sandeep V. Pakhale	Anatomy	
3.	Dr. Prafulla S. Dakhane	Anatomy	
4.	Dr. Shubhangi Ghule	Anatomy	
5.	Dr. Tushar R. Patil	Anatomy	
6	Dr. Udit Agrawal	Biochemistry	
7	DR A NAGENDRA	Micro	
8	DR Vinod Kathrotia/Jadhav	Physiology	
9	Dr. Maria Khatoon	Physiology	MCh
10	Dr Yogita Hiwarkar	Comm. Medicine	
11	Dr. Dilip Dhekale	Comm. medicine	
12	Mr. Vijay P More	PSM	
13	Dr. Savita S. Nyndhe	Microbiology	
14	Dr Gaikwad B K	Anesthesia	
15	Dr. Rutuja R. Kakad	Anesthesiology	
16	Dr. Nikhil Joshi	Surgery	
17	Dr. C.A. Kale	medicine	
18	Dr. Lakhwinder Singh	Orthopedics	
19	Dr. Anita K. Nagargoje	Psychiatry	
20	Dr. Tejendra Chauhan	Neurology	
21	Dr. Devendra Patil.	MEDICINE	
22	Dr. Kailash nagpure	Microbiology	

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 3058569
Fax: (0257) 3058548

IEC/ 2015/ **Minutes of Meeting**

DATE: 16/11/2015

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Prof. Nitinchandra V. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. Narayan S. Arvikar	Member	
4.	Dr. Sunil V. Chaudhari	Member	
5.	Dr. (Mrs) Maya N. Arvikar	Member	
6.	Dr. Rahul P. Bhavasar	Member	
7.	Dr. Smita C. Pathade	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. S. A. T. Subzwari	Member	
10.	Mrs. Jyotsna P. Bhirud	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the changing of members of IEC from the previous members.

ii) To discuss the requirements of registration of newly formed IEC, DUPMCH.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. Invited the new chairman and new member secretary.
3. Issues like arranging the training about Basics of GCP (good clinical practice) in clinical research by all members which a major requirement for registration of IEC, DUPMCH.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari

Member Secretary

DUPMCH

Institutional Ethics Committee, DUPMCH, JALGAON

It is an independent body whose responsibility is to ensure the protection of rights, safety and well-being of human participants involved in a **clinical trial** and to provide public assurance of that protection.

The IEC will review scientific and ethical aspects of all types of **Research Studies Involving Human Participants.**

Member list

Sr. No.	Member Name	Designation
1.	Prof. Nitinchandra V. Patil	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. Narayan S. Arvikar	Member
4.	Dr. Sunil V. Chaudhari	Member
5.	Dr. (Mrs) Maya N. Arvikar	Member
6.	Dr. Rahul P. Bhavasar	Member
7.	Dr. Smita C. Pathade	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant Warke	Member
10.	Mrs. Jyotsna P. Bhirud	Member

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 25/02/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 27/02/2016 at 3.00 pm
All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Prof. Nitinchandra V. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. Narayan S. Arvikar
4	Dr. Sunil V. Chaudhari
5	Dr. (Mrs) Maya N. Arvikar
6	Dr. Rahul P. Bhavasar
7	Dr. Smita C. Pathade
8	Adv. Satish Gadge
9	Dr. S. A. T. Subzwari
10	Mrs. Jyotsna P. Bhirud
11	Dr. Ravindrakumar. L. Bakal
12	Dr. Prashant S. Warke
13	Mr. Sunil R. Bonde

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical College & Hospital, Jalgaon kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ **Minutes of Meeting**

DATE: 27/02/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Sandeep V. Pakhale	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Sunil R. Bonde	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the changing of members of IEC from the previous members.

ii) To discuss the requirements of registration of newly formed IEC, DUPMCH.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for registration of IEC, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 08/03/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 09/03/2016 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Sr No	Name
1	Dr. Ravindrakumar. L. Bakal
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Sandeep V. Pakhale
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Dr. Rahul P. Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant S. Warke
10	Mr. Sunil R. Bonde

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ **Minutes of Meeting**

DATE: 09/03/2016

Location: Department of Pharmacology
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Sandeep V. Pakhale	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Sunil R. Bonde	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Department of Pharmacology.

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the requirements of registration of newly formed IEC, DUPMCH.

Minutes of meeting:-

1. All the required documents are collected and signed by all the members of IEC, DUPMCH.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 3058557 Fax : 3058548 E-Mail Id : dupmcj@yahoo.in

Date:- 13/07/2016

CIRCULAR

All teaching staff members are informed that Workshop on 'Basics of GCP' (Good clinical Practice) is arranged for Institutional Ethics Committee (IEC) members on 16 July 2016 from 9 am to 5 pm by Dept of Pharmacology, Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh .

Workshop is for 25 members. Those who are interested in membership of IEC can attend the workshop.

DEAN
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax [redacted] E-Mail Id : dupmcj@yahoo.in

Workshop on Basics of GCP
At
Dr Ulhas Patil Medical College and hospital, Jalgaon
Conducted by
2366657 2366648

Dept of Pharmacology & Therapeutics, Dr Ulhas Patil Medical College and hospital, Jalgaon, 425001

Date: 16TH JULY 2016, from 9.00 am to 5.00pm.

Program

Time	Topic	Speaker
8.00 pm-9.15 pm	Breakfast	
9.15 pm-9.30 pm	Introduction of participants	
9.30 – 10.15 pm	Overview of GCP: Principles and Practice	Dr. DEVENDRA CHAUDHARI* Member Secretary, IEC, DUPMCH
10.15 am -11.15 am	Ethical Guidelines: ICMR guidelines Schedule Y Indian GCP guidelines	Dr. DEVENDRA CHAUDHARI* Member Secretary, IEC, DUPMCH
11.15am -11.30am	**Tea break**	
11.30 pm-12.15 pm	Investigators responsibilities	Dr. Ravindrakumar L. Bakal** Chairperson IEC, DUPMC
12.15 pm – 1.00 pm	Sponsor's responsibilities	Dr. Ravindrakumar L. Bakal** Chairperson IEC, DUPMC
1.00pm-2.00pm	**Lunch Break**	
2.00pm-3.00pm	Informed Consent Process	Dr. PAKHALE*** Member IEC, DUPMCH
3.00pm-4.00pm	Ethics Committee: Roles and responsibilities	Dr. DEVENDRA CHAUDHARI* Member Secretary, IEC, DUPMCH
4.00pm-4.30pm	Serious Adverse Event Reporting	Dr. DEVENDRA CHAUDHARI* Member Secretary, IEC, DUPMCH
4.30pm-5.00pm	Feedback	

* Professor, Department of Pharmacology & Therapeutiics, DUPMCH.
** Principal, KYDSCT's College of Pharmacy, NH6 Jalgaon Bhusaval Road, Sakegaon, Jalgaon
***Professor, Deparment of Anatomy, DUPMCH.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in
Date:- 15/07/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/07/2016 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Sandeep V. Pakhale
5	Dr. Milind P. Joshi
6	Dr. Smita c.Pathade
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ Minutes of Meeting

DATE: 17/07/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Sandeep V. Pakhale	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the changing of members of IEC from the previous members.

ii) To discuss the requirements of registration of newly formed IEC, DUPMCH.

Minutes of meeting:-

1. Members are changed from previous members and new members are invited.
2. New chairman and members are been invited.
3. Issues about requirement for registration of IEC, DUPMCH are discussed.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted]2366657 Fax :[redacted]2366648 E-Mail Id : dupmcj@yahoo.in
Date:- 05/08/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 08/08/2016 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Sandeep V. Pakhale
5	Dr. Milind P. Joshi
6	Dr. Smita c.Pathade
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ Minutes of Meeting

DATE: 08/08/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Sandeep V. Pakhale	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the changing the name of thesis topic of pathology PG according to the guidelines sent by MUHS.

Minutes of meeting:-

1. IEC members discussed the issue regarding the change in thesis topic name according to the guidelines of MUHS.
2. The thesis topic name changed according to MUHS guidelines and member secretary and chairman signed on the documents of submission to MUHS.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

MUHS
महाराष्ट्र आरोग्य विद्यापीठ, नाशिक
Maharashtra University of Health Sciences, Nashik
(An ISO 9001: 2008 Certified University)
वाणी - दिंडोरी रोड, मुंगसरे, नाशिक - ४२२ ००४, Vani-Dindori Road, Mhasrul, Nashik- 422 004
EPABX: 0253-2539100-300, Fax – 0253-2539200, Phone: 0253-2539234
E-mail : pgacademic@muhs.ac.in Web.: www.muhs.ac.in

No. MUHS/PG-T/E1/1823 /2016 Date: 18/07/2016

To,
The Dean / Principal,
Godavari Foundation's
Dr. Uttam Patil Medical
College & Hospital, G.No.35
Jalgaon Bhusawal Road,
Jalgaon - 42 5 309.

Sub.: Deficiencies observed in the proposal (S) of Synopsis Approval.

Ref : Your letter No GF/DUPMC & H/PG-Adm/2015-16/543 Date- 22-12-2015

Sir/Madam,

With reference to the subject cited above, I am directed to inform you that, the following proposal(s) (No.----------) for approval of Title & Synopsis for the students admitted for Academic Year 2015-16 has been received by the University, on primary scrutiny, University has observed some deficiencies which are stated as below

Sr. No.	Name of Student	Subject Speciality	Deficiency
01	Do. Bhangale Harshada	MD Pathology	city name mentioned in the Title & Synopsis.
02			submit the corrected copy of Appendix 'A' & 'B'
03			Ref MUHS Notification dtd 23/11/2012 Point no 10 state that Name, City, College area & any sort of identity not to be mentioned in Title.
04			

Therefore, you are required to fulfill the deficiency & re-submit the proposal(s) of above mentioned student, along with requisite late fee (ignore if already submitted) for further necessary action. Liability of non-compliance on the subject & thereby causing any academic loss to the students shall rest with the Dean/Principal of the College.

Yours Sincerely

Dr Uttam Patil Medical Colleg
and Hospital, Jalgaon Kh
Inward No.: 174
Date: 26/07/2016

Academic Section (PG)

Students
Gmform
PG students

C:\Users\acad29\Desktop\With out letter head of HOD format letters\compliance letters 1.doc

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 12/10/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 14/10/2016 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Sandeep V. Pakhale
5	Dr. Milind P. Joshi
6	Dr. Smita c.Pathade
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ Minutes of Meeting

DATE: 14/10/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Sandeep V. Pakhale	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S.Y Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the appointment of new member instead of Dr. Sandeep V. Pakhale who resigned.

Minutes of meeting:-

1. Dr. Amrut Mahajan is appointed as new member instead of Dr. Sandeep V. Pakhale who resigned and his name is submitted to head of institution (dean).

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax : [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 22/11/2016

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 25/11/2016at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar I.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita c.Pathade
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ **Minutes of Meeting**

DATE: 25/11/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S.Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the dissertation protocol of pathology pg student for submission to university.

Minutes of meeting:-

1. The dissertation protocol of Dr. RUNALI, First yr Pathology PG, was discussed and some changes are suggested according to guidelines by IEC members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

APPENDIX 'B'

REPORT OF ETHICS COMMITTEE

Department	: Pathology
Candidate admitted year	: 2016
Course and Subject	: M.D.Pathology
College Name & Address	:Dr.UlhasPatil Medical College,Jalgaon.

Date: 29/11/16.....

Reference No. .....

To,

Dr. Runali D. Mendhe.
Department ofPathology
Dr.UlhasPatil Medical College,Jalgaon.

Sub: Research Proposal of entitled "**STUDY OF HAEMATOLOGICAL AND BIOCHEMICAL FINDINGS IN PATIENTS OF CHRONIC KIDNEY DISEASE AND ITS CLINICAL CORELATION.**"

(Title & Synopsis of Dissertation)

Ref:- GF/DUPMC&H/PG-Adm/2016-17/159/31-12-2016

(Letter/ Proposal of Student)

Dear Student,

The above mentioned research proposal of Title & Synopsis of Dissertation was discussed in the Ethics Committee meeting held on **(Date)**.....25/11/16..... at our College.

Ethics Committee has unanimously approved your Title & Synopsis of Dissertation.

This work will be done under the guidance and supervision of your guideDr.VilasMahadeoraoSangole.The Title is Recommended for study by the student from Date: ...29/11/16.....

(Signature)

Dr....R.L. Bakal....

Chairperson, Ethics Committee

Dr.UlhasPatil Medical College,Jalgaon

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ Minutes of Meeting

DATE: 08/09/2017

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Mr. Bapurao M. Bite	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To appoint new member in place of member who has resigned

4.1

Minutes of meeting:-

1. One Member of IEC resigned so new member was appointed in his place - Mr.Bapurao Motiram Bite
2. All ~~committees~~ formalities required for IEC Member ship were done .
3. Introduction of new Member to remaining member & IEC

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 04/05/2017

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 05/05/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Dr. Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2017/ Minutes of Meeting

DATE: 05/05/2017

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the dissertation study of pathology pg student for submission to university.

Minutes of meeting:-

1. Progress of study was checked
2. Changes suggested in last meeting were confirmed
3. It was ensured that study was undertaken as per ICE guiedlines .

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 07/09/2017

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 08/09/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Mr. Bapurao M. Bite
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 04/05/2017

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 05/05/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Dr. Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2017/ Minutes of Meeting

DATE: 05/05/2017

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.36 pm

4 AGENDA

4.1 To discuss the dissertation study of pathology pg student for submission to university.

Minutes of meeting:-

1. Progress of study was checked
2. Changes suggested in last meeting were confirmed
3. It was ensured that study was undertaken as per ICE guiedlines .

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 07/09/2017

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 08/09/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Mr. Bapurao M. Bite
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2016/ **Minutes of Meeting**

DATE: 08/09/2017

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Mr. Bapurao M. Bite	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To appoint new member in place of member who has resigned

4.1

Minutes of meeting:-

1. One Member of IEC resigned so new member was appointed in his place - Mr.Bapurao Motiram Bite
2. All ~~committees~~ formalities required for IEC Member ship were done .
3. Introduction of new Member to remaining member & IEC

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 04/06/2018

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 05/06/2018 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Mr. Bapurao M. Bite
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2018/ Minutes of Meeting

DATE: 05/06/2018

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Mr. Bapurao M. Bite	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of an Intern titled 'PREVALENCE OF SUBSTANCE ABUSE IN INTERNS OF PRIVATE MEDICAL COLLEGE'

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 1st July 2018 to 31st Aug 2018. The implication of the study assets the prevalence of substance abuse in medical student that will help to run a treatment programs related to substance abuse in future course on interns in any medical college in India.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

4 AGENDA

4.1 To discuss the research study of an Intern titled 'PREVALENCE OF SUBSTANCE ABUSE IN INTERNS OF PRIVATE MEDICAL COLLEGE'

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 1st July 2018 to 31st Aug 2018. The implication of the study assets the prevalence of substance abuse in medical student that will help to run a treatment programs related to substance abuse in future course on interns in any medical college in India.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
PREVALENCE OF SUBSIANCE ABUSE IN INTERNS OF PRIVATE MEDICAL COLLEGE

2. Name of the Principal Investigator/ Under/~~Post~~ graduate student:
SIDDHARTHA MILIND MURMEKAR

3. Name of the co-investigator/ UG/PG guide/Trial monitor (if applicable)
MANSI MADAN

4. i) Signature of Principal investigator/ UG/~~PG~~ student:
S.Murmekar

ii) Signature of co-investigator/ UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON I.E.C.

MEMBER SECRETARY I.E.C.

Professor & HOD
Dept. Of Pharmacology
Dr.Ulhas Patil Medical College,
& Hospital, Jalgaon Kh.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 MONTHS (1st July to 30th August 2018)

7) Risk factor for the patient (give details):

A) ProceduraIL:

NA

B) Adverse drug reaction (ADRs):

NA

C) Invasive investigations (if any):

NA

D) Explain the measures to counter the above risk factors:

NA

8) **Details about research project**

(a) Objectives: To SUBSTANTIATE THE EXTENT OF SUBSTANCES OF ABUSE IN INTERNS & FIND THE PEVALENCE AMONG SAME GROUP

(b) Current knowledge about the research subject:

(c) Research plan: QUESTIONAIRRE BASED STUDY

(d) Implications: ASSESSING PREVALENCE OF SUBST ABUSE & SPECIFY SECTORS TO RUN FUTURE PROGRAMS FOR SAME GROUP

(e) Conflict of interest:

(f) Risk factors: NA

(g) Bibliography/List of references: Attached

9) **Details of financial burden involved and how it will be met:** AROUND ₹2000,

10) **Whether the research project is sponsored:** YES/NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) **Any other relevant information:**

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

S Murhekar

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. SIDDHARTHA MURHEKAR .....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
PREVALENCE OF SUBSTANCE ABUSE IN INTERNS OF PRIVATE MEDICAL COLLEGE

Kindly do the needful.

S Murhekar

(SIDDHARTHA MURHEKAR)
(Candidate name and signature)

(Guide name and signature)

DR. MAYUR K. MUTHE.
Professor & HOD
Department of Psychiatry
Dr.Ulhas Patil Medical College
& Hospital,Jaygaon Ta.Jalgaon

(HOD name and Signature with Dept. seal)

REFERENCE ID : 2018-00533

TITLE :

Prevalence of substance abuse in interns of a private medical college.

INTRODUCTION :

The ever increasing competition, the changing of social behavior and the need for fast-growing world has to pay the price and it has come in terms of the stress in not only the workers to complete their monthly goal but it has also galloped the medical fraternity from which it has now become impossible to separate medical students and substance abuse which comes in one or another form.

The drug is not only dangerous by itself but also augments the action if combined with other less harmful substance and may in the end prove lethal.

Adding to the problems, concurrent use of cocaine, morphine and iv substances is frequently associated with immune system dysfunction and increased vulnerability to infections, including risk for HIV infection. Chronic cocaine and psychostimulant abuse may exacerbate preexisting disorders such as hypertension and cardiac disease.

A wide knowledge of drugs and a detailed pros and cons list is available to the medical students hikes the probability of inclination towards substance abuse.

Studies conducted worldwide including India have estimated a prevalence rate of substance abuse to be around 20- 40% [1] among students from various streams including the medical field.

Commonly found abuse drugs in medical students are classified as [2]

1) CNS depressants:

- Alcohol and Alcoholic beverages
- Tranquilizers

2) CNS stimulants:

- Cocaine
- Amphetamine and methamphetamines
- Caffeine
- Nicotine

3) Opioids :

- Morphine

4) Canabinoids :

- Weed

5) Hallucinogens :

- LSD

In the quest of securing a post graduate seat, the aspirants are exposed to tremendous stress and poor stress coping teachings, adding to it, long working hours(12-18 hours) [3] have proven to be an important cause for abuse.

OBJECTIVES:

To substantiate the extent of substances of abuse in Interns(completed IIIrd Prof of MUHS,Nashik) of a private medical college and find the prevalence among the same group.

METHODOLOGY:

This will be a study based on the students of Godavari Foundation's Dr. Ulhas Patil Medical College And General Hospital. (Recognized by MCI and affiliated to MUHS Nashik), Jalgaon Khurd.

The methods used will be:

1) Alcohol Use Disorders Identification Test (AUDIT) [4]

2) Administration of a structured questionnaire for Drug Abuse designed and validated in-house. [5]

Sample size: A sample size of 100 students will be studied.

Duration of study: The duration of study will be 2 months.

The 100 students will be asked a set of questions which will be done in 2 steps:

1) An AUDIT for Alcohol and Alcoholic Beverages Abuse

The responses will be recorded on a 5 point scale (Least to Most) based on a 12 months history.

ITEM	5-Point Scale(LEAST TO MOST)
1) How often do you have a drink containing Alcohol?	Never (0) to 4+ per week(4).
2) How many drinks do you have on a typical day?	1 or 2 (0) to 10+ (4)
3) How often do you have 6 or more drinks	Never (0) to daily or almost daily(4)

on one occasion?	
4) How often during the last year have you found that you were not able to stop drinking once you had started?	Never (0) to daily or almost daily(4)
5) How often during the last year have you needed a first drink the morning to get yourself going after a heavy drinking session?	Never (0) to daily or almost daily(4)
6) How often in the last year have you failed to do what was normally expected from you because of drinking?	Never (0) to daily or almost daily(4)
7) How often in the last year have you had a feeling of guilt or remorse after drinking?	Never (0) to daily or almost daily(4)
8) How often in the last year have you been unable to remember what happened the night before because of drinking?	Never (0) to daily or almost daily(4)
9) Have you or someone been injured as a result of your drinking?	No (0) to yes, during the last year(4)
10) Has any relative of friend of yours ben concerned about you drinking or suggested that you should cut it down?	No (0) to yes, during the last year(4)

The AUDIT will be scored by simply summing the values associated with the endorsed response. A score >8 may include harmful alcohol use.

2) A Ques onnaire for Drug abuse substances .

This will include the following Ques ons:

1) Which are the drugs you have been consuming the past one year?
2) What changes you feel have been brought in your body after the consump on of these drugs?

The rest would be in a YES/ NO format

1) Have you ever used drugs other than for medical reasons?
2) Have you abused prescription drugs?
3) Have you had "blackouts" or "flashbacks" after consump on of drugs?
4) Did you ever feel bad or guilty about using drugs?
5) Did you face any trouble at work after using drugs?

6) Have you experienced withdrawal symptoms after you stopped use of drugs?
7) Have you had any medical problems as a result of drug use? (Example: Bleeding, hepatitis, convulsions, memory loss)
8) Did you ever feel the need to cut short the use of drugs?
9) Have you gone to seek any suggestions or medical help related to drug abuse?
10) Have you been involved in a treatment program specifically for drug use?

These responses will be recorded and accordingly, the results will be interpreted.

INCLUSION CRITERIA:

Male and female students (Interns) working presently at Dr. Ulhas Patil Medical College and General Hospital.

EXCLUSION CRITERIA:

1.Individuals who are unwilling to participate in the study.

2. Students who have not passed IIIrd prof examination.

COLLECTION, PRESENTATION AND INTERPRETATION OF DATA:

After the study period, results of the study will be compiled and thus the data will be analysed and an interpreta on will be derived.

IMPLICATIONS:

1)This study will help us to assess the prevalence of substance abuse in Medical Students.

2) It will make it easier to run any treatment programs related to substance abuse in future course on interns in any medical college throughout India.

REFERENCES:

[1]Substance abuse amongst the medical graduates of a developing country, Student IJMR, Subhar Medical College and Hospital Meerut, India.

[2]Classification of Abuse substances by NIDA - National Institute on Drug Abuse.

[3]Average of Interns work , Dr Ulhas Patil Medical College And General Hospital ,Jalgaon

[4]Addiction Research Foundation Author : Harvey A Skinner, Washington, PHD.

[5]Harrison's Manual of Medicine , 19th Edition, Psychiatry and Substance Abuse, Page no. 1082

QUESTIONAIRRE FOR STS REPORT

Hello Doctors, myself Siddhartha Murhekar, 2014 batch, DUPMC, Jalgaon is the investigator of a study conducted for **ICMR STS report**. The study is based on "Prevalence of substance abuse in interns "of a medical college.

Before you start, please read this carefully. Your college has been randomly selected to take part in this study. You are one of the students par cipa ng in the study. The information you give will contribute to a better understanding of young people like yourself. **DO NOT write your name** on this questionnaire. The answers you give will be kept private. **No one will know what you write.** The questions that are asked about your background will only be used to describe the types of students completing the survey. The information will not be used to find out your name. **No names will ever be reported**. Answer the questions based on what you really do and know. **Please answer as truthfully as you can**. Completing the survey is voluntary. If you are not comfortable answering a question, just leave it blank. (Try not to leave many blanks☺). This is **not a test**. There are no right and wrong answers. If you do not find an answer that fits exactly, **mark the one that comes closest**. Please read every question and mark your best answer for each question by putting a tick (☑) in the box given. Also, write in your answer in readable handwriting wherever mentioned. We

hope you find the questionnaire interesting. If you have a question, please raise your hand. **Thank you very much for your help.**☺

BACKGROUND INFORMATION ABOUT YOURSELF.

1. Where do you live? (City/Village)

_____

2. What is your gender?

☐ Male ☐ Female

3. Age (in years) _____

4. Family size _____

The next questions ask about your PARENTS. If you were raised by foster parents, step-parents or others, answer for them (the most important in raising you).

5. What is the highest level of schooling your father attained?

☐ Illiterate
☐ Reading and writing
☐ Elementary school
☐ High school
☐ Associate diploma
☐ Bachelor's degree
☐ Master's degree and higher
☐ Middle school
☐ High school diploma

6. What is the highest level of schooling your mother attained?

☐ Illiterate ☐ Reading and writing ☐ Elementary school

☐ Middle school ☐ High school ☐ Bachelor's degree

☐ Master's degree and higher

7. What is your father's occupation?

☐ Clerk ☐ Self-employed ☐ Unemployed ☐ Retired

☐ Others (Please write it down)_____

The following questions are about CIGARETTE SMOKING

8. On how many occasions (if any) have you smoked cigarettes? Mark one box in each row.

	0	1-2	5-20	20 or more
a) In your lifetime	☐	☐	☐	☐
b) During the last 12 mths	☐	☐	☐	☐

The next questions are about ALCOHOLIC BEVERAGES, including beer, wine and spirits.

9. On how many occasions (if any) have you had any alcoholic beverage to drink (more than just a few sips)? Mark one box in each row.

	0	1-2	5-20	20 or more
a) In your lifetime	☐	☐	☐	☐
b) During the last 12 mths	☐	☐	☐	☐

☐ Middle school ☐ High school ☐ Bachelor's degree

☐ Master's degree and higher

7. What is your father's occupation?

☐ Clerk ☐ Self-employed ☐ Unemployed ☐ Retired

☐ Others (Please write it down)_____

The following questions are about CIGARETTE SMOKING

8. On how many occasions (if any) have you smoked cigarettes? Mark one box in each row.

	0	1-2	5-20	20 or more
a) In your lifetime	☐	☐	☐	☐
b) During the last 12 mths	☐	☐	☐	☐

The next questions are about ALCOHOLIC BEVERAGES, including beer, wine and spirits.

9. On how many occasions (if any) have you had any alcoholic beverage to drink (more than just a few sips)? Mark one box in each row.

	0	1-2	5-20	20 or more
a) In your lifetime	☐	☐	☐	☐
b) During the last 12 mths	☐	☐	☐	☐

10. Answer the following questions in AUDIT(Alcohol Use Disorders Identification Test). 5-Point Scale

(LEAST TO MOST)

1) How often do you have a drink containing alcohol?

☐ Never (0) ☐1

☐2 ☐3

☐4+

2) How many drinks do you have on a typical day?

☐ Never (0) ☐1

☐2 ☐3

☐4+

3) How often do you have 6 or more drinks on one or more occasions?

☐ Never (0) ☐1

☐2 ☐3

☐4+

5) How often during the last year have you needed a rst drink the morning to get yourself going after a heavy drinking session?

☐ Never (0) ☐1

☐2 ☐3

☐4+

6) How often in the last year have you failed to do what was normally expected from you because of drinking?

☐ Never (0) ☐1

☐2 ☐3

☐4+

7) How often in the last year have you had a feeling of guilt or remorse after drinking?

☐ Never(0) ☐1
☐2 ☐3
☐4+

8) How often in the last year have you been unable to remember what happened the night before because of drinking?

☐ Never(0) ☐1
☐2 ☐3
☐4+

9) Have you or someone been injured as a result of your drinking?

☐ Never(0) ☐1
☐2 ☐3
☐4+

10) Has any relative of friend of yours been concerned about you drinking or suggested that you should cut it down?

☐ Never (0) ☐1
☐2 ☐3
☐4+

Each of the following questions can have more than one possible answer, so mark as many answers as you consider correct.

11. Have you used IN YOUR LIFE any of the following drugs? Mark in the box.

☐ Ecstasy/ MDMA/ Disco biscuit

☐ Sleeping pills/Barbs/Barbiturates/Benzodiazepines

☐ Hashish/Weed/Smoke/GreenGrass/Ganja/Hemp

☐ Analgesics like ibuprofen pills(more than 6tabs/day)

☐ Crack/Cocaine/Snow/Coca

☐ Amphetamine/Metamphetamine

☐ Morphine/God's drug

☐ LSD/Yellow Sunshine/had bad trips

☐ Heroin/Dope/Brown Sugar/Smack

☐ Opium/Fentanyl/Pain Killer

☐Angel Dust/Phenycyclidine(PCP)

☐Marijuana/Cannabis/Black Mamba

☐Inhalants(eg. Fevibond, Glue, Whitener, Petrol)

☐Vicodin(the one House MD uses ☺)/Hydrocodone

☐Dextromethorphan/Codeine/ Cough Syrup Overuse (more than 1 bottle of 100mg/100ml/day)

☐ Tobacco/Vimal®/Miraj®/Gaichap®/Kharra

☐ Psychological medication (used for treatment of psychological diseases; eg. Methylphenidate(Inspiral®)/ Modafinil/Anti-depressants)

☐ Do you use any other drugs?

1) If yes, name them_____

12. Age at first smoking, alcohol or any other substance use?

(In Years) _____

13. Why did you start using drugs?

Have you ever used drugs? ☐Yes ☐No

If you answered "yes", please answer the following questions

☐I used once for curiosity
☐If an acute condition occurs, I use drugs to improve my general condi on
☐Disability in resolving routine problems
☐Low cost of drugs
☐I use drugs to improve my memory before exams
☐ I use drugs so I can give public lectures
☐I use drugs following family disputes
☐I use drugs to achieve feeling of happiness and joy
☐I use drugs to win sport competitions
☐Presence of an addicted person in residential/educational place
☐Others (Please write)

_____
_____
_____

15. What physical or psychological changes occur after drug use?

In my opinion, drug use causes-

(Please mark one of these items in the boxes given below)

		Agree	No Comment	Disagree
1	Transient euphoria	☐	☐	☐
2	Improved memory and learning ability	☐	☐	☐
3	Depression	☐	☐	☐
4	Improvement in some somatic diseases	☐	☐	☐
5	Increase in self confidence	☐	☐	☐
6	Better acceptability by friends	☐	☐	☐

What is your idea about addictive potential of drugs **in my opinion**

a	Using some drugs like hashish are not addictive	YES	NO
b	Even with using drugs for 1 time, there is a possibility of becoming addicted	YES	NO
c	Occasional use is ok	YES	NO

If you use drugs for any other reason, please men on it

_____

16. How often do you use drugs?

a) Once a day
b)More than once a day
c) Once a week
c)Several times a week
d)Others (Please write it down)

_____

17. In what occasions do you use drugs?

☐Before exams
☐Before doing sports
☐On the street
☐At parties
☐At home
☐During stressful duty hours in ward
☐Others (Please write down)_____

18. Have you ever had any of the following problems? Mark all the boxes that apply in each row.

	Never	Yes, because of my alcohol use	Yes, because of my drug use	Yes, for reasons other than alcohol or drug use
a) Quarrel or argument	☐	☐	☐	☐
b) Scuffle or fight	☐	☐	☐	☐
c) Accident or injury	☐	☐	☐	☐
d) Loss of money or other valuable items	☐	☐	☐	☐
e) Damage to objects or clothing	☐	☐	☐	☐
f) Problems in your relationship with your parents	☐	☐	☐	☐
g) Problems in your relationship with your friends	☐	☐	☐	☐
h) Problems in your relationship with your teachers	☐	☐	☐	☐
i) Performed poorly at school or work	☐	☐	☐	☐
j) Victimized by robbery or the	☐	☐	☐	☐
k) Trouble with police	☐	☐	☐	☐
l) Hospitalized or admitted to an emergency room	☐	☐	☐	☐
m) Engaged in sex you regretted the next day	☐	☐	☐	☐
n) Engaged in unprotected sex	☐	☐	☐	☐

19. How much do you think people risk harming themselves (physically or in other ways), if they do the following? Mark one box in each row.

☐No risk

☐Slight risk

☐Moderate risk

☐Great risk

20. Have you ever received any information regarding drug use/abuse/its complications?

☐Yes
☐No
☐Not sufficient

21. Did you seek any help regarding need for drug/ alcohol use problems/ any rehabilitation visits?

_____

_____

_____

Thank you for taking the time to answer these questions☺. We hope you found them interesting and hope that you did not forget to answer any of them that you intended to answer.

------***------

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 01/11/2018

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 02/11/2018 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Smita C. Pathade
7	Mr. Bapurao M. Bite
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2018/ Minutes of Meeting

DATE: 02/11/2018

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Smita C. Pathade	Member	
7.	Mr. Bapurao M. Bite	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of assistant professor of Pharmacology titled 'ASSIGNMENT BASED LEARNING OF DIFFERENT DOSAGE FORM AND NEWER AND TARGETED DRUG DELIVERY SYSTEM AMONG UNDERGRADUATE STUDENTS'

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 12th Nov 2018 to 20th Nov 2018. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation**
   Assignment based learning of different dosage forms & Newer & targeted drug delivery system among undergraduate medical students.
2. **Name of the Principal Investigator/ ~~Under~~/Post graduate student:**
   Dr. Rahul Prakash Bhavsar
3. **Name of the co-investigator/ UG/PG guide/Trial monitor (if applicable)**
   Dr. Devendra R. Chaudhari
   ~~Dr. Dr. Yogita D~~ Sulakshane
4. **i) Signature of Principal investigator/ UG/PG student:**

   ii) Signature of co-investigator/ UG/PG guide/Trial monitor:

   iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

iv) **Signature of HOD of other Departments involved (with seal):**

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decjsion of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) **Place where research work will be carried out**

✓ (A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and it's analysis:**

1 Week.

7) **Risk factor for the patient** (give details):

A) ProceduralL: — Nil.

B) Adverse drug reaction (ADRs):

Nil

C) Invasive investigations (if any):

Nil

D) Explain the measures to counter the above risk factors:

Nil

8) **Details about research project** (Is attached Separately)

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) **Details of financial burden involved and how it will be met:** - Self.

10) **Whether the research project is sponsored:** YES/NO✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) **Any other relevant information:** N.A.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr, Rahul P. Bhavsar ....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Assignment based learning of Different dosage form & Newer & targeted Drug delivery system among undergraduate medical student.

Kindly do the needful.

(Candidate name and signature)

Dr Chandekar D. R.

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 17/11/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/11/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ **Minutes of Meeting**

DATE: 18/11/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of professor of psychiatry DR. ANUP RATHI titled **'Study of scociodemographic profile and psychopathology of mentally and physically handicapped children and their parents'**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from 18th November 2019 to 17th June 2020. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
Study of Sociodemographic Profile and Psychopathology of mentally and Physically Handicapped Children and their parents.

2. Name of the Principal Investigator/ Under/Post graduate student:
Dr. Anup Katti

3. Name of the co-investigator/ UG/PG guide/Trial monitor (if applicable)
Dr. Pankaj Sanghvi
Dr. Sapan Kadia Karia

4. i) Signature of Principal investigator/ UG/PG student:

ii) Signature of co-investigator/ UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept_____

1) Date of Receipt by IEC (submission of application) _____
2) Date of resubmission to IEC _____
3) Date of IEC meeting _____
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED. _____
5) IEC decision conveyed on date _____

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A)At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

6 months (Jan 2020 to July 2020)

7) Risk factor for the patient (give details)

A) Procedural:

Nil

B) Adverse drug reaction (ADRs):

NIL

C) Invasive investigations (if any):

NIL

D) Explain the measures to counter the above risk factors:

N.A.

8) Details about research project

(a) Objectives: To study demography & Psychopathology of mentally & Physically handicapped children & their Parents

(b) Current knowledge about the research subject:

(c) Research plan: Application of Questionnaire & Scales

(d) Implications: will help in supporting handicapped children and their Parents.

(e) Conflict of interest: NIL

(f) Risk factors: NIL

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met: Personal Expense

10) Whether the research project is sponsored: YES/NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

NIL

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V)
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Anup Rathi hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
STUDY OF SOCIODEMOGRAPHIC PROFILE & PSYCHOPATHOLOGY OF PHYSICALLY AND MENTALLY HANDICAPPED CHILDREN & THEIR PARENTS

Kindly do the needful.

(Dr. ANUP RATHI)
(Candidate name and signature)

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 13/02/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 14/02/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Mr. Bapurao M. Bite
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ **Minutes of Meeting**

DATE: 14/02/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Mr. Bapurao M. Bite	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of assistant professor of Pharmacology titled '**Ask them early, catch them soon! Awareness among medical students regarding pre-diabetes, early diabetes and its early management by life style changes. Screening to evaluate them for pre-diabetes and diabetes**'

4.2 To discuss the appointment of new member instead of **Dr. Smita C. Pathade** who resigned.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 14th Feb 2019 to 14th June 2019. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.
6. Dr. Nilesh Bendale is appointed as new member instead of **Dr. Smita C. Pathade** who resigned and his name is submitted to head of institution (dean).

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

4 AGENDA

4.1 To discuss the research study of assistant professor of Pharmacology titled '**Ask them early, catch them soon! Awareness among medical students regarding pre-diabetes, early diabetes and its early management by life style changes. Screening to evaluate them for pre-diabetes and diabetes**'

4.2 To discuss the appointment of new member instead of **Dr. Smita C. Pathade** who resigned.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 14th Feb 2019 to 14th June 2019. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.
6. Dr. Nilesh Bendale is appointed as new member instead of **Dr. Smita C. Pathade** who resigned and his name is submitted to head of institution (dean).

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation ASK THEM EARLY, CATCH THEM SOON! Awareness Among Medical Students Regarding Pre-Diabetes, Early-Diabetes And Its Early Management By Lifestyle Changes. Screening Them To Evaluate For Pre-Diabetes And Diabetes.

2. Name of the Principal Investigator/
Under/Post graduate student:
BHOSLE KARTIKI SHIVAJI

3. Name of the co-investigator/
UG/PG guide/Trial monitor
(if applicable)
DR. VAISHALI BABURAO NAGOSE

4. i) Signature of Principal investigator/
UG/PG student:
BHOSLE KARTIKI

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:
Dr. Vaishali B. Nagose.

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) _____
2) Date of resubmission to IEC _____
3) Date of IEC meeting _____
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: _____

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

5 MONTHS

7) Risk factor for the patient (give details):

A) ProceduraIL:

1. HEMATOMA FORMATION.
2. VASOVAGAL SYNCOPE.

B) Adverse drug reaction (ADRs):

—

C) Invasive investigations (if any):

—

D) Explain the measures to counter the above risk factors:

1. VENOUS BLOOD WITHDRAWAL WILL BE DONE BY TRAINED TECHNICIAN WITHOUT DOING ANY COUNTER PUNCTURE OF THE VEIN.
2. THE SUBJECTS WILL BE HYDRATED PROPERLY BEFORE THE PROCEDURE.

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

—

—

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature of Principal Investigator.

---

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, ~~Dr.~~ BHOSLE KARTIKI SHIVAJI hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis ASK THEM EARLY, CATCH THEM SOON! Awareness Among Medical Students Regarding Pre Diabetes, Early Diabetes An Its Early Management By Lifestyle Changes. Screening Them To Evaluate The For Pre Diabetes And Diabetes.

Kindly do the needful.

BHOSLE KARTIKI SHIVAJI

(Candidate name and signature)

DR. VAISHALI BABURAO NAGOSE

(Guide name and signature)

DR VILAS MAHADEORAO SANGOLE

(HOD name and Signature with Dept. seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 12/04/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 15/04/2019 at 3.30 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 12/04/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 15/04/2019 at 3.30 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ Minutes of Meeting

DATE: 15/04/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh P. Bendale	Member	
7.	Dr. Rahul P. Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	S. Y. Patil

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the appointment of new member instead of **Mr. Bapurao M. Bite** who resigned.

Minutes of meeting:-

1. **Dr. Rahul P. Bhavasar** is appointed as new member instead of **Mr. Bapurao M. Bite** who resigned and his name is submitted to head of institution (dean).

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmci@yahoo.in

Date:- 25/05/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 27/05/2019 at 3.30 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ Minutes of Meeting

DATE: 27/05/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ **Minutes of Meeting**

DATE: 27/05/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of assistant professor of Pharmacology titled **'A knowledge altitude and practice study among undergraduate medical and nursing students regarding the basic knowledge of trauma evaluation and its management in traffic accidents'**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted from 1st june 2019 to 31st Aug 2019. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
   A Knowledge, Attitude and Practice (KAP) Study among under-graduate medical and nursing students regarding the basic knowledge of trauma evaluation and its management in traffic accidents.
2. Name of the Principal Investigator/
   Under/Post graduate student:
   ABHIJEET RAJENDRA BHOMBADE
3. Name of the co-investigator/
   UG/PG guide/Trial monitor
   (if applicable)
   DR. DEEPAK PRAKASH AGRAWAL.
4. i) Signature of Principal investigator/
   UG/PG student:
   Abhi
   ii) Signature of co-investigator/
   UG/PG guide/Trial monitor:
   Professor & HOD
   Dept. of Orthopedics
   Dr. Ulhas Patil Medical College
   & Hospital Jalgaon kh,Jalgaon
   iii) Signature of HOD of Principal Investigator/UG/PG student:
   (with seal)
   Professor & HOD
   Dept. of Orthopedics
   Dr. Ulhas Patil Medical College
   & Hospital Jalgaon kh,Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of applicatfon) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

✓(A)At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

3 MONTHS (1st June 2019 to 31st Aug 2019)

7) Risk factor for the patient (give details):

A) ProceduralL:

–

B) Adverse drug reaction (ADRs):

_____ –

C) Invasive investigations (if any):

_____ –

D) Explain the measures to counter the above risk factors:

_____

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/~~NO~~

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).

11) Any other relevant information:

_____

___

_____

___

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. ABHIJEET BHOMBADE.....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
A Knowledge, attitude & practice (KAP) study among Undergraduate medical & nursing students regarding the basic knowledge of trauma evaluatio and its Management in traffic accidents.

Kindly do the needful.

ABHIJEET RAJENDRA BHOMBADE

(Candidate name and signature)

(Guide name and signature)
Professor & HOD
Dept. of Orthopedics
Dr. Ulhas Patil Medical College
& Hospital Jalgaon kh,Jalgaon

(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Orthopedics
Dr. Ulhas Patil Medical College
& Hospital Jalgaon kh,Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 17/07/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/07/2019 at 3.30 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr.Ravindrakumar l.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr.Prashant M. Warke
10	Mr.Prabhakar M. Jangale
11	Mr.Sandesh Y.Patil

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ **Minutes of Meeting**

DATE: 18/07/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of associate professor of pathology titled **'Formative Assessment in pathology by means of objective structured practical examination (OSPE) in II MBBS students' and III yr student titled 'Study of the effects of a first person shooter game on various aspects of cognition'**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from 22nd July 2019 to 05th Aug 2019 and 1st August 2019 to 30th Sept 2019 respectively. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

Formative Assessment in Pathology by means of OSPE Objective Structured Practical Examination (OSPE) in MBBS Students.

2. Name of the Principal Investigator/ Under/Post graduate student

DR Vaishali Baburao Nagose

3. Name of the co-investigator/ UG/PG guide/Trial monitor (if applicable)

Dr Vipin Narendra Todase.

4. i) Signature of Principal investigator/ UG/PG student:

ii) Signature of co-investigator/ UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

Professor & HOD
Dept. of Pharmacology
Dr. Ulhas Patil Medical College
Jalgaon (MS) India

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A)At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

15 days (22nd July to 05th Aug 2019)

7) Risk factor for the patient (give details):

A) Procedural: Not applicable

B) Adverse drug reaction (ADRs):

Not applicable

C) Invasive investigations (if any):

D) Explain the measures to counter the above risk factors:

8) Details about research project - present - synopsis.

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Baburao Nagore hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Formative assessment in Pathology by means of Objective structured Practical Examination (OSPE) in II MBBS Students.

Kindly do the needful.

Dr Vaishali B. Nagore.
(Candidate name and signature)

Dr. Vipin Todase
Co-investigator
(Guide name and signature)

Dr Devendra
(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh., Jalgaon

Godavari Foundation's

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date : 17/09/2019

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/09/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2019/ **Minutes of Meeting**

DATE: 18/09/2019

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of associate professor of pathology titled **'Squash cytology an effective tool in intra-operative diagnosis of the central nervous system lesion'**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from 18th September 2019 to 17th September 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation**
   Squash cytology as effective tool in intraoperative diagnosis of the Central Nervous System Lesions.

2. **Name of the Principal Investigator/ ~~Under/Post graduate student:~~**
   Dr. Vaishali Nagose.

3. **Name of the co-investigator/ ~~UG/PG guide/Trial monitor~~ ~~(if applicable)~~**
   Dr. Swapnil Patil (Bajirao)

4. i) **Signature of Principal investigator/ ~~UG/PG student:~~** Nagose.

   ii) **Signature of co-investigator/ ~~UG/PG guide/Trial monitor:~~**

   iii) **Signature of HOD of Principal Investigator/UG/PG student:**
   (with seal) Dr. V. A. Sangle
   Professor & HOD
   Dept. of Pathology
   Dr. Ulhas Patil Medical College & Hospital
   Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

✓
(A)At DUPMC&H ~~(B) Outside DUPMC&H.~~

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 years.

7) Risk factor for the patient (give details): – None

A) ProceduraIL:

_____

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

_____

_____

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Nagose hereby submitting synopsis of my research protocol/ ~~PG dissertation~~ for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Squash Cytology - an effective tool in intraoperative diagnosis for Central Nervous System lesions.

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose
(Candidate name and signature)

BBPatil
(~~Guide~~ name and signature)

(HOD name and Signature with Dept. seal)

Co investigator -
(Dr. Swapnil Bajirao Patil).

(Dr. V. M. Sangole)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
   Knowledge Attitude and Awareness Study Among Medical Interns Regarding Transmission of Blood Born Infections and Precautions to prevent them in Routine Practise and Special Medical Procedures.
2. Name of the Principal Investigator/ Under/Post graduate student:
   KARTIKI · SHIVAJI · BHOSLE.
3. Name of the co-investigator/ UG/PG guide/Trial monitor (if applicable)
   DR. VAISHALI NAGOSE.
4. i) Signature of Principal investigator/ UG/PG student:
   ii) Signature of co-investigator/ UG/PG guide/Trial monitor:
   iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

For Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

3 months.

7) Risk factor for the patient (give details):

A) ProceduralL:

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/(NO)

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

_____

_____

_____

_____

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

KARTIKI SHIVAJI BHOSLE.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. KARTIKI BHOSLE .....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Knowledge Attitude and Awareness Study Among Medical Interns Regarding Transmission of Blood Borne Infections and precautions to prevent them in Routine practise and Special Medical Procedures.

Kindly do the needful.

KARTIKI · SHIVAJI · BHOSLE
(Candidate name and signature)

Dr. Vaishali Nagose
(Guide name and signature)

For Nagose

(HOD name and Signature with Dept. seal)

Professor & HOD
Dept. of Pathology
Dr Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 26/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 28/12/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2020/ Minutes of Meeting

DATE: 28/12/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the case report of Dr. Vaishali Nagose titled "the first case of proliferative fasciitis of tongue coexistent with squamous cell carcinoma case report of a rare lesion."

Minutes of meeting:-

1. Case report was discussed under – title, introduction, case history, discussion and conclusion, and consent form.
2. As per guidelines for publication of case report only the consent of patient is sufficient and that has been taken by the case reporter.
3. The permission was granted to publish the case report by the committee members.
4. Application form for publication of case report was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 4.00 pm

Meeting Actual End: 4.30 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) -425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 21/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 22/12/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2020/ Minutes of Meeting

DATE: 22/12/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the SOP's to introduce it to all new IEC members.

4.2 To prepare the time table for PG students for presentation of their thesis topic.

Minutes of meeting:-

1. All SOP's were distributed to all present IEC Members.
2. All members presented their respective SOP's and stated the importance of that SOP.
3. In this way the SOP's discussed among all present members.
4. Finalization of SOP's done in the meeting.
5. All members finalized the date of presentation of thesis topics of PG students and prepared the time table for them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 4.00 pm

Meeting Actual End: 4.30 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

The First case of Proliferative Fasciitis of Tongue Coexistant with squamous cell Carcinoma: Case report of a rare lesion.

2. Name of the Principal Investigator/
~~Under/Post graduate student~~

Dr. Vaishali Nagose
Professor Pathology.

3. Name of the co-investigator/
~~UG/PG guide/Trial monitor~~
~~(if applicable)~~

4. i) Signature of Principal investigator/
UG/PG student:

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

Professor & Head
Department of Pathology
D.U.P.M.C.,Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A)At DUPMC&H ✓ (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 moths.

7) Risk factor for the patient (give details):

A) ProceduralL: No.

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

] as in synopsis.

9) Details of financial burden involved and how it will be met: —

10) Whether the research project is sponsored: ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).

11) Any other relevant information: None.

_____

_____

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Nagose. .....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
The first case of Proliferative fasciitis of tongue, coexistant with SCC. - Case report of a rare lesion. (squamous cell carcinoma)

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose
(Candidate name and signature)

Nagose. Dr. Vaishali Nagose
(Guide name and signature)

(HOD name and Signature with Dept. seal)
Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

The First case of Proliferative Fasciitis of tongue Coexistant with squamous cell Carcinoma: case report of a rare lesion.

2. Name of the Principal Investigator/
~~Under/Post-graduate student:~~
Dr. Vaishali Nagore
Professor Pathology.

3. Name of the co-investigator/
~~UG/PG guide/Trial monitor~~
~~(if applicable)~~

4. i) Signature of Principal investigator/
UG/PG student: Nagore.

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only)

Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A)At DUPMC&H ✓ (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 moths.

7) Risk factor for the patient (give details):

A) ProceduralL: No.

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) **Details about research project**

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

] as in Synopsis

9) **Details of financial burden involved and how it will be met:** ——

10) **Whether the research project is sponsored:** ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).

11) **Any other relevant information:** None.

_____

_____

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Nagose. .....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
The first case of Proliferative fasciitis of tongue, coexistant with SCC. - Case report of a rare lesion. (squamous cell carcinoma)

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose

(Candidate name and signature)

Nagose. Dr. Vaishali Nagose

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

The First case of Proliferative Fasciitis of Tongue Coexistant with squamous cell Carcinoma: Case report of a rare lesion.

2. Name of the Principal Investigator/
~~Under/Post graduate student:~~
Dr. Vaishali Nagose
Professor Pathology.

3. Name of the ~~Co~~-investigator/
~~UG/PG guide/Trial monitor~~
~~(if applicable)~~

4. i) Signature of Principal investigator/
UG/PG student: Nagose

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

Professor & Head
Department of Pathology
D.U.P.M.C., Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only)

Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A)At DUPMC&H ✓ (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 moths.

7) Risk factor for the patient (give details):

A) ProceduralL: No.

B) Adverse drug reaction (ADRs):

C) Invasive investigations (if any):

D) Explain the measures to counter the above risk factors:

8) **Details about research project**

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

as in Synopsis.

9) **Details of financial burden involved and how it will be met:** —

10) **Whether the research project is sponsored:** ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).

11) Any other relevant information: None.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Nagose. .....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
The first case of proliferative fasciitis of tongue coexistant with SCC:- Case report of a rare lesion. (squamous cell carcinoma)

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose

(Candidate name and signature)

Nagose. Dr. Vaishali Nagose

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Professor & Head
Department of Pathology
D.U.P.M.C.,Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmci@yahoo.in

Date:- 06/01/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 07/01/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2020/ Minutes of Meeting

DATE: 07/01/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of associate professor of pathology Dr. Vaishali Baburao Nagose, titled **'Case based learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate Students)'**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from 10th Jan 2020 to 10th March 2020. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation

Case Based learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate students)

2. Name of the Principal Investigator/
~~Under~~/~~Post graduate student~~:

Dr. Vaishali Baburao Nagose.

3. Name of the co-investigator/
~~UG~~/~~PG~~ guide/~~Trial~~ monitor
(if applicable)

Dr. Vipin Todase.

4. i) Signature of Principal investigator/
UG/PG student:

ii) Signature of co-investigator/
UG/PG guide/Trial monitor:

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

✓

(A)At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 months.

7) Risk factor for the patient (give details):

A) ProceduralL: Not applicable.

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) **Details about research project** as per synopsis attached.

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) **Details of financial burden involved and how it will be met:** Nom

10) **Whether the research project is sponsored:** ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) **Any other relevant information:** ___

_____

_____

Enclosures: Not applicable -

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Thagose.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Vaishali Baburao Nagose .....hereby submitting synopsis of my research protocol/ ~~PG dissertation~~ for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis

Case Based Learning as a means of reforming Pathology Teaching in second MBBS (Undergraduate) Students.

Kindly do the needful.

Dr. Vaishali Nagose.
(Candidate name and signature)

—
(Guide name and signature)

(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 16/09/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 17/09/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 04 / 2020/ **Minutes of Meeting**

DATE: 17/09/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATION AURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID -19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL ."**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from October 2020 to December 2020 The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATION AURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID -19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL ."**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from October 2020 to December 2020 The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE) OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval. (*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation** - Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults And Field Workers In Prevention Of Covid-19: A Randomized Controlled Prospective Clinical Trial

2. **Name of the Principal Investigator:** Dr. Milind B. Nikumbh, Dean, Government Ayurved College, Jalgaon

3. **Name of the co-investigator** –Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon

4. **i) Signature of Principal investigator:**

   ii) Signature of co-investigator:

   iii) Signature of HOD of Principal Investigator:

   Dr. Milind B. Nikumbh
   Dean, Govt. Ayurved College
   Jalgaon

   iv) Signature of HOD of other Departments involved (If any):

(For IEC Office use only) Sr. No_____

Dept .....

1) Date of Receipt by IEC (submission of application) 12.09.2020
2) Date of resubmission to IEC .....
3) Date of IEC meeting 17.09.2020
4) Decision of IEC: APPROVED
5) IEC decision conveyed on date: 17.09.2020

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and its analysis: - 3 Months from the date of allotment of first subject

7) Risk factor for the patient (give details):

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

8) Details about research project

(a) Objectives:

1. To study the efficacy of specifically designed innovative ayurvedic treatment regimen in suspected high-risk adults and field workers.
2. To create awareness among the subjects regarding Ayurveda and Yoga in preventing COVID-19.

(b) Current knowledge about the research subject: The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities.

(c) **Research plan:** The total cases of COVID warriors turned positive or symptomatic on 17th Sept 2020 from Jalgaon city is around 1500 which includes, doctors, nurses, police officers, paramedical staff etc. Considering this as a population, the sample size for the present research can be calculated as 383 using Raosoft® online sample size calculator [5] with 5% margin of error and 95% confidence level. So, to avoid further bias and errors, the sample size for the present study will be 300 (150 in each group).

Selection of subjects: - The individuals who were at high risk and in immediate contact with the COVID-19 subjects, do or **do not show any signs and symptoms of flu** will be the population for the current study. 300 such healthy individuals will be selected randomly and will be divided into two groups (A-Trial & B-Control group 150 each).

After procuring the informed written Consent, first group-A (Trial group;

n=150) will be managed with specifically designed innovative ayurvedic treatment regimen and the other group -B (Control group; n=150) will be kept under observation. The trial will be conducted for the 30 days. And the entire duration of the study including the allotment and analysis of the results will be 3 months.

(d) Implications: None

(e) Conflict of interest: None Declared

(f) Risk factors: Stated in the Research Protocol.

(g) Bibliography/List of references:

1. Cyranoski D. "We need to be alert": scientists fear second coronavirus wave as China's lockdowns ease. Nature 2020 [Epub ahead of print]. DOI: 10.1038/d41586-020-00938-0
2. World Health Organization. Off label use of medicines for COVID 19. WHO reference number: WHO/2019-nCoV/Sci_Brief/Off-label_use/2020.1 Online document at: https://apps.who.int/iris/bitstream/handle/10665/331640/WHO-2019-nCoV-Sci_Brief-Off-label_use-2020.1-eng.pdf, accessed May 8, 2020.
3. World Health Organization. WHO SOLIDARITY Clinical trial for COVID 19 treatments. Online document at: https://www.who.int/solidarity-clinical-trial-for-covid-19-treatments, accessed April 8, 2020
4. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf (Accessed on 27.04.2020)
5. http://www.raosoft.com/samplesize.html (Accessed on 27.04.2020)

9) **Details of financial burden involved and how it will be met:**

Sr. No.	Expenditure	Justification	Approximate Amount
1	Raw Drugs & Medicine	The contents of Innovative Ayurveda Medicines (IAM-Dip bags) will cost around Rs 15/3gm. Therefore, for approximate cost of total medicine per subject will be around Rs. 1100 and for 150 subjects will be Rs 2 Lakh	200000
2	Preparation of Medicines	Preparation of the specified coarse powder and inner and outer packaging.	50000
3	Purchasing Poly-propylene non-woven material	Size of dip bag will be 5.5x6cm. Approximate costs per dip bag will be around Rs 1.5/ bag.	15000
4	Lab investigations including RT-PCR (in case if the subject is positive for Rapid antigen test.)	RT-PCR is conducted only if the patient is showing the signs and symptoms of COVID-19. The cost decided by Government of Maharashtra for private laboratories is Rs. 1200 per subject.	360000
5	Stationary	A4 size papers for Case Research form (20 pages each), information leaflets, Test reports etc.	50000
6	Printing	Printing of Case Research form (20 pages each), information leaflets, Test reports etc.	50000
7	Travelling	Petrol expenditure for first and last personal visit to the subjects at their respective offices and work places.	35000
8	Liability Insurance	Liability Insurance for 800 subjects in case of any ADR (Approximately Rs. 175 per subject)	140000
9	Miscellaneous	For sudden and unexpected expenditure during the research in case if the budget of above 8 heads is exhausted.	30000
	Total		**930000**

The financial support will be provided by the Maharashtra University of Health Sciences, Nashik under the Extra Mural Research Scheme.

10) **Whether the research project is sponsored:** YES
Sponsoring authority: Maharashtra University of Health Sciences, Nashik

11) Any other relevant information: Attached herewith is Detail Research Protocol

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.
(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) Newspaper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Milind B. Nikumbh hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee. I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers In Prevention Of Covid-19: A Randomized Controlled Prospective Clinical Trial

Kindly do the needful.

Government Ayurved College • Jalgaon •

Dr. Milind. B. Nikumbh
Dean
Government Ayurved College,
Jalgaon

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

TO BE PRINTED ON OFFICIAL LETTER-HEAD OF OFFICE

TO WHOM SO EVER IT MAY CONCERN

CONSENT LETTER

We have no objection to conduct clinical trials of the trial drugs under the studytitled **"Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial"** on COVID patients admitted in ourcentre for the purpose of research sponsored by Maharashtra University of Health Sciences Nashik.

The investigators will have full access to the patients in our centre for examination of the patientunder the trial in the proposed study.

We hereby give consent to **Dr. Milind B. Nikumbh, Dean, Government Ayurved College& Hospital, Jalgaon,**the PrincipalInvestigator of the Research project titled**"Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial"** for the same.

In-charge
COVID Hospital/ Center

TO BE PRINTED ON IEC LETTERHEAD

Institutional Ethics Committee (IEC) Report

OutwardNo.: IECDUPMCH/04/2020 Date: 17/09/2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled **Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial**

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) [please state the name of the IEC] .....IEC DUPMCH..... was held on .....17/09/2020 at (time) ..3:00 P.M... in the (Venue) ....DUPMC Jalgaon....with(Name).Dr. Raindra kumar Bakal was Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
01	Dr Raindra kumar Bakal	Chairman	Principal	
02	Dr Devendra R. Chaudhari	Member Secretary	Prof & Head	M.D.
03	Dr (Mrs) M. N. Avhikar	Member	Prof & Head	M.D.
04.	Dr Nilesh Bendale	Member	Asso. Prof	M.D.
05.	Adv Satish Gadge	Member	Legal adv. sor	LLM
06.	Dr. Prashant S. Warke	Member	Principal MBA	MBA

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

The IRB/IEC approves the project entitled **Clinical Evaluation of Efficacy of Specifically Designed Innovative Ayurvedic Treatment Regimen for Suspected High-Risk Adults and Field Workers in Prevention of Covid-19: A Randomized Controlled Prospective Clinical Trial**

It is understood that the research project will be conducted under your direction, in a total of 300 (150 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IRB/IEC of an appropriate amendment. The IRB/IEC expects that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,

Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

It is understood that the research project will be conducted under your direction, in a total of 300 (150 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IRB/IEC of an appropriate amendment. The IRB/IEC expects that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,

Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

CLINICAL EVALUATION OF EFFICACY OF SPECIFICALLY DESIGNED INNOVATIVE AYURVEDIC TREATMENT REGIMEN FOR SUSPECTED HIGH-RISK ADULTS AND FIELD WORKERS IN PREVENTION OF COVID-19: A RANDOMIZED CONTROLLED PROSPECTIVE CLINICAL TRIAL

CLINICAL TRIAL PROTOCOL

Submitted to Maharashtra University of Health Sciences, Nashik

Principal Investigator	Co-investigator(s)	AYUSH Associate
Dr. Milind B. Nikumbh Dean, Government Ayurved College, Jalgaon	Dr. Sandeep V. Binorkar Assistant Professor Government Ayurved College, Jalgaon	Dr. Leena Badgujar, MO, NRHM, AYUSH, Jalgaon Dr. Bhushan Deo CHO, NHM, Jalgaon

Government Ayurved College & Hospital, Jalgaon

Introduction:

The coronavirus disease 19 (COVID-19) pandemic is exceptional and unprecedented in several aspects and has challenged health care systems all over the world. At present, the global momentum is unrelieved and further catastrophe is still anticipated.[1] The outbreak of this virus was primarily reported in Wuhan, China in December 2019 [2] The principal cause behind this pandemic is newly identified sever acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The experiences and lessons learnt from the earlier severe acute respiratory syndrome (SARS) epidemics appear inadequate and resulted in call for better approaches and strategies in public health and medical care. Contemporary mainstream medicine is the vanguard and struggling to rheostat the menace. The existing prophylactic measures are inadequate, and suggested possibilities such as hydroxychloroquine (HCQ) are still under investigation. [3]

Globally mortality rates and sever complications have been high among those with hypertension, cardiovascular disease or type 2 diabetes. However, COVID-19 infection exhibits a wide clinical course affected by lower respiratory tract infection and gastrointestinal system. The role of the immune response in COVID-19 infection disease is under study but there is evidence suggesting that lung damage could be more immune-mediated rather than directly virus-induced. In adding, recent data from various laboratories suggest that SARS maybe a systemic disease with widespread extrapulmonary dissemination.

The prophylactic and therapeutic potential of traditional and complementary medicine systems such as Ayurveda and Yoga is not really being considered during this crisis and global hunt for effective preventive and treatment measures.

Therefore, the present study is being attempted to evaluate the knowledge and practices from Ayurveda that might be effectively utilized in the prophylaxis and adjuvant therapy of COVID-19 which may support the quarantined patients of COVID-19 and field workers including doctors, paramedical staff, Police staff, municipal corporation and other related personals in preventing the disease thereby improving the quality of standard care.

AIM & OBJECTIVES:

To study the efficacy of specifically designed innovative ayurvedic treatment

regimen in suspected high-risk adults and field workers in preventing the disease.

Objectives:

1. To study the efficacy of specifically designed innovative ayurvedic treatment regimen in suspected high-risk adults and field workers.
2. To create awareness among the subjects regarding Ayurveda and Yoga in preventing COVID-19.

Research Question

Is specifically designed innovative ayurvedic treatment regimen is effective in preventing suspected high-risk adults and field workers turning positive?

Research Hypothesis

The specifically designed innovative ayurvedic treatment regimen is effective in preventing suspected high-risk adults and field workers turning positive.

Review of Literature:

Innovative Ayurveda Medicines (IAM-Dip bags):

This preparation is combination of various herbs which are proven to exhibit immuno-modulator properties, as well as their effects on various respiratory disorders. Dip bags are the innovative methods to server the medicine in required quantity and also easy to carry at workplace thereby avoiding the laborious and tedious method of preparing a decoction.

Material and Methods:

The specifically designed innovative ayurvedic treatment regimen includes following combination of Ayurveda drugs treatment.

Particular	Details
Innovative Ayurveda Medicines (IAM-Dip bags)	Each 3 gm Dip Bags containing – 1. Shunthi (*Zingiber officinale*) 1 part, 2. Hingu (Ferula assafoetida) 1 part, 3. Maricha (*Piper nigrum*) ¼ part, 4. Twak (*Cinnamomum zeylanicum*) 1part, 5. Tulasi (*Ocimum sanctum*) 1part, 6. Amalaki (*Emblica officinalis*) 1part, 7. Haridra (*Curcuma longa*) 1/10th part, 8. Lavang (*Syzygium aromaticum*) 1part, 9. *Jatiphal (Myristica fragrans) 1/20th part,* 10. *Nimbu satwa* (Citrus limon) 1/20th part 11. Saindhava (Rock salt) 1/5th part

	All herbs packed in dip bag boiled at 100°C for 3 minutes in 200 ml of water and reduced to half. 100 ml BID After breakfast 8:00 am and in the evening at 5:00pm
Duration of the Treatment	30 days
Follow up	Day -0, 7, 15, 22 and 31st

The raw drugs for innovative dip tea bags will be procured from the GMP certified Yugandhar Pharma from Nashik and a certification for authentication and standardization will be obtained from them.

The standard Poly-propylene non-woven material with the permeance (23.9×10^{-5}m/s) will be used for the preparation of dip tea bags containing 3 gm of combination of the contents stated above. The coarse powder of the content (40 mesh size) will be used to fill in the tea bags (5.5x6cm).

Methodology:

It is known fact under the Drugs and Cosmetics Rules of 1945, that there is no regulatory provision for clinical trials in alternative medicine. Therefore, the clinical research in Ayurveda should also be conducted as per AYUSH guidelines and clinical research or ICMR guidelines. Consequently, after acquiring the approval by the scientific advisory bodies and Institutional Ethics Committee, the research protocol will also be registered with the CTRI, the Clinical Trials Registry of India.[4]

Sample Size: -

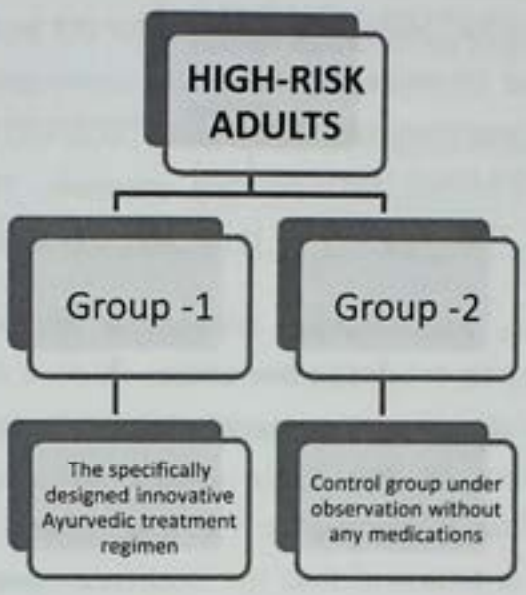
The total cases of COVID warriors turned positive or symptomatic on 17th Sept 2020 from Jalgaon city is around 1500 which includes, doctors, nurses, police officers, paramedical staff etc. Considering this as a population, the sample size for the present research can be calculated as 383 using Raosoft® online sample size calculator [5] with 5% margin of error and 95% confidence level. So, to avoid further bias and errors, the sample size for the present study will be 300 (150 in each group).

Selection of subjects: -

The individuals who were at high risk and in immediate contact with the COVID-19 subjects, do or **do not show any signs and symptoms of flu** will be the population for the current study. 300 such healthy individuals will be selected

randomly and will be divided into two groups (A-Trial & B-Control group 150 each).

After procuring the informed written Consent, first group-A (Trial group; n=150) will be managed with specifically designed innovative ayurvedic treatment regimen and the other group -B (Control group; n=150) will be kept under observation. The trial will be conducted for the 30 days. And the entire duration of the study including the allotment and analysis of the results will be 3 months.



Time schedule:

First two months will be utilized for the allotment and selection of the subjects for the study and the 3rd month will be utilized for the assessment of the results.

Inclusion criteria: -

1. High risk individuals such as doctors, paramedical staff, police staff, municipal corporation staff and other suspected personals who were in contact with the COVID-19 subjects.
2. Individuals who do not show any signs and symptoms of flu.
3. Individuals who shows Negative rapid antigen / Negative RT-PCR test for COVID-19.
4. Individuals between the Age- above 18 years below 50 years

Exclusion criteria: -

1. Subjects who are COVID 19 positive and in critical stage.
2. Subjects below 18 years above 50 years of age.
3. Pregnant and lactating women.
4. Subjects having an active malignancy

5. Subjects giving history of significant cardiovascular event < 12 weeks prior to randomization
6. Subjects having a chronic disease such as active tuberculosis, Hepatitis B or C, or HIV

Institutional Ethics Committee & Scientific Advisory Approval: -

The necessary approval from Institutional Ethics Committee (IEC) of Dr. Ulhas Patil Medical College & Hospital, Jalgaon is obtained for the study via vide letter No. IEC, DUPMCH/04/20, dated 17.09.2020. This Ethics committee is registered under rule 122DD of the Drugs and Cosmetic Rules 1945 (ECR/852/Inst/MH/2016). The copy of IEC approval is attached herewith the proposal. The research will also be registered to Clinical Trial Registry of India and CTRI no. will be obtained in due course.

Clinical Trial Insurance coverage benefits: -

As per the recommendation and suggestion of the Institutional Ethics Committee (IEC), each participant of the study should be insured against the harms experienced by him/her if any during the trial, mainly Adverse Drug Reactions (ADR). Therefore, it is proposed that the insurance coverage will be obtained for the participants from appropriate insurance agency supporting bulk general insurance for such clinical trials.

OBSERVATIONS: -

Observations and responses of the participants will be collected through google forms on daily basis until the day of completion of duration of research project.

EXPECTED BUDGET ALLOCATIONS:

Sr. No.	Expenditure	Justification	Approximate Amount
1	Raw Drugs & Medicine	The contents of Innovative Ayurveda Medicines (IAM-Dip bags) will cost around Rs 15/3gm. Therefore, for approximate cost of total medicine per subject will be around Rs. 1100 and for 150 subjects will be Rs 2 Lakh	200000
2	Preparation of Medicines	Preparation of the specified coarse powder and inner and outer packaging.	50000
3	Purchasing Poly-propylene non-woven material	Size of dip bag will be 5.5x6cm. Approximate costs per dip bag will be around Rs 1.5/ bag.	15000
4	Lab investigations including RT-PCR (in case if the subject is positive for Rapid antigen test.)	RT-PCR is conducted only if the patient is showing the signs and symptoms of COVID-19. The cost decided by	360000

		Government of Maharashtra for private laboratories is Rs. 1200 per subject.	
5	Stationary	A4 size papers for Case Research form (20 pages each), information leaflets, Test reports etc.	50000
6	Printing	Printing of Case Research form (20 pages each), information leaflets, Test reports etc.	50000
7	Travelling	Petrol expenditure for first and last personal visit to the subjects at their respective offices and work places.	35000
8	Liability Insurance	Liability Insurance for 800 subjects in case of any ADR (Approximately Rs. 175 per subject)	140000
9	Miscellaneous	For sudden and unexpected expenditure during the research in case if the budget of above 8 heads is exhausted.	30000
	Total		**930000**

The above proposed budget is showing approximated values. In case if any amount remained in the account after the completion of the research, the same will be highlighted and reimbursed while submitting the audit report and utilization certificate.

Results and Conclusions: -

The results will be obtained based on observations after applying Paired and Unpaired 't' test and other statistical tools; conclusions will be drawn accordingly.

REFERENCES

1. Cyranoski D. "We need to be alert": scientists fear second coronavirus wave as China's lockdowns ease. Nature 2020 [Epub ahead of print]; DOI: 10.1038/d41586-020-00938-0
2. World Health Organization. Off label use of medicines for COVID 19. WHO reference number: WHO/2019-nCoV/Sci_Brief/Off-label_use/2020.1 Online document at: https://apps.who.int/iris/bitstream/handle/10665/331640/WHO-2019-nCoV-Sci_Brief-Off-label_use-2020.1-eng.pdf, accessed May 8, 2020.
3. World Health Organization. WHO SOLIDARITY Clinical trial for COVID 19 treatments. Online document at: https://www.who.int/solidarity-clinical-trial-for-covid-19-treatments, accessed April 8, 2020.
4. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf (Accessed on 27.04.2020)
5. http://www.raosoft.com/samplesize.html (Accessed on 27.04.2020)

****

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 22/09/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 23/09/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 05 / 2020/ Minutes of Meeting

DATE: 23/09/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **DR MILIND B. NIKUMBH** titled **"A CLINICAL EVALUATION OF EFFICACY OF AYURVEDIC TREATMENT REGIMEN AS AN ADD-ON THERAPY WITH MODERN MEDICINE IN COVID 19 - A RANDOMIZED, MULTI-CENTER, SINGLE BLIND, PROSPECTIVE CLINICAL STUDY ."**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from October 2020 to December 2020. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website: http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE) OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval. (*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation** - A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study

2. **Name of the Principal Investigator/ Under/Post graduate student:** Dr. Milind B. Nikumbh, Dean, Government Ayurved College, Jalgaon

3. **Name of the co-investigator/ UG/PG guide/Trial monitor** –Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon

4. **i) Signature of Principal investigator:**

   ii) Signature of co-investigator:

   iii) Signature of HOD of Principal Investigator:

   iv) Signature of HOD of other Departments involved (with seal):

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

(For IEC Office use only) Sr. No_____

Dept .....

1) Date of Receipt by IEC (submission of application) 17.09.2020
2) Date of resubmission to IEC .....
3) Date of IEC meeting 23.09.2020
4) Decision of IEC: APPROVED
5) IEC decision conveyed on date: 23.09.2020

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) **Place where research work will be carried out**

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and its analysis: -** 3 Months from the date of allotment of first subject

7) **Risk factor for the patient** (give details):

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

8) Details about research project

(a) Objectives:

Primary Objectives:

- To assess the efficacy of Ayurvedic treatment regimen in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache)

Secondary Objectives

- To assess the clinical safety of Ayurvedic treatment regimen in the patients of positive coronavirus Disease.

(b) Current knowledge about the research subject: The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities.

(c) Research plan: **Number of Patients to be completed in the clinical trial (Sample Size)** : 380 (190 Patients in each group) The total active cases all over India on 27th April 2020 are around 27,000. Considering this as a population, the sample size for the present research can be calculated as 380 using Raosoft® online sample size calculator [9] with 5% margin of error and 95% confidence level.

Groups: -The subjects will be divided randomly in two groups (190 Patients in each group), viz. Trial and Control. The Trial group (Group -1) will be administered with Ayurvedic treatment regimen for COVID-19 along with the standard modern medicines and control group (Group-2) will be provided with the standard treatment protocol only which is followed in the modern medical hospitals.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and its analysis: -** 3 Months from the date of allotment of first subject

7) **Risk factor for the patient** (give details):

A) Procedural L: None

B) Adverse drug reaction (ADRs): Trial drugs are all Herbal Medicine. ADR Not reported so far.

C) Invasive investigations (if any): - None

D) Explain the measures to counter the above risk factors: Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

8) Details about research project

(a) Objectives:

Primary Objectives:

- To assess the efficacy of Ayurvedic treatment regimen in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache)

Secondary Objectives

- To assess the clinical safety of Ayurvedic treatment regimen in the patients of positive coronavirus Disease.

(b) Current knowledge about the research subject: The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities.

(c) Research plan: **Number of Patients to be completed in the clinical trial (Sample Size)** : 380 (190 Patients in each group) The total active cases all over India on 27th April 2020 are around 27,000. Considering this as a population, the sample size for the present research can be calculated as 380 using Raosoft® online sample size calculator [9] with 5% margin of error and 95% confidence level.

Groups: -The subjects will be divided randomly in two groups (190 Patients in each group), viz. Trial and Control. The Trial group (Group -1) will be administered with Ayurvedic treatment regimen for COVID-19 along with the standard modern medicines and control group (Group-2) will be provided with the standard treatment protocol only which is followed in the modern medical hospitals.

(d) Implications: None

(e) Conflict of interest: None Declared

(f) Risk factors: Stated in the Research Protocol.

(g) Bibliography/List of references:

1. "WHO Director- General's opening remarks at the media briefing on COVID-19, 11th March 2020
2. "Statement on the second meeting of the International Health Regulation (2005) Emergency Committee regarding the outbreak of Novel Corona Virus (2019-nCoV)" World Health Organization.
3. "WHO Director- General's opening remarks at the media briefing on COVID-19, 11th March 2020
4. "COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)" ArcGIS Johns Hopkins University
5. www.who.int/emergencies/diseases/novel-coronavirus-2019 (Accessed on 27.04.2020)
6. "Here Comes the Corona Virus Pandemic: Now, after many fire drills, the world may be facing a real fire". Editorial New York Times 29th Feb 2020
7. IMF Blog. "The great lockdown: Worst Economic downturn since the Great Depression." IMF Blog.
8. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf (Accessed on 27.04.2020)
9. http://www.raosoft.com/samplesize.html(Accessedon 27.04.2020)
10. Vagbhata - Ashtang Hridaya – Sarvaangasundara and Ayurveda Rasaayana, Collated by Anna Moreshwara Kunte, 9th Edition Chaukhamba Orientalia Publication, Varanasi. 2002
11. Sharangdhar Samhita, Englsih Translation by Shrikanthamurthy, 4th Edn, Chaukhambha Orientalia, Varanasi, 2001
12. Charak Samhita Vidyothini hindi commentary by Satya Narayan Shastri, Chaukhambha bharati academy Varansi Edition2001
13. Shahedur Rahman1,* and Rashida Parvin2 Therapeutic potential of Aegle marmelos (L.)-An overview, Asian Pac J Trop Dis. 2014 Feb; 4(1): 71–77. doi: 10.1016/S2222-1808(14)60318-2
14. Azad Rajaram et.al, Anti-inflammatory profiilr of (L) Correa (Bilwa) with special reference to young roots growing in different parts of India, Journal of Ayurveda and integrative medicine, 9(2):2018, p.90-98
15. Marc Maurice cohen, Tulsi- Ocimum sanctum: A Herb for all reasons, Journal of Ayurveda and integrative medicine, 5(4):2014, p.251-259
16. K Srinivasan et.al, Antinociceptive and Antipyretic Activities of Pongamia Pinnata Leaves, Phytother Res. 2003 Mar;17(3):259-64. doi: 10.1002/ptr.1126.
17. Khuda F, Iqbal Z, Khan A, Zakiullah, Nasir F, Shah Y. Antiinflammatory activity of the topical preparation of Valeriana wallichii and Achyranthes aspera leaves. Pak J Pharm Sci 2013; 26(3):451-4.
18. Krishna Kumar Ganta et. al, Anti-HCV Activity from Semi-purified Methanolic Root Extracts of Valeriana Wallichii, Phytother Res. 2017 Mar;31(3):433-440. doi: 10.1002/ptr.5765. Epub 2017 Jan 12.
19. Amrendra KumarChaudhary et.al., Cedrus deodara (Roxb.) Loud.: A Review on its Ethnobotany, Phytochemical and Pharmacological Profile, Pharmacognosy Journal, 3(23):2011, 12-17
20. Christine Tara Peterson et.al., Therapeutic Uses of Triphala in Ayurvedic Medicine, The Journal of Alternative and Complementary Medicine Volume 23, Number 8, 2017, pp. 607–614. DOI: 10.1089/acm.2017.0083
21. Zhang XJ, He LJ, Lu Q, Li DY. Zhongguo Zhong Yao Za Zhi. 2016;41(4):619-623. doi:10.4268/cjcmm20160412
22. Gupta et. al., Molecular Biology and Pharmacognosy of Beneficial Plants, Lenin Media Private Limited, Delhi, India, 2017, p.52-64
23. Hasan et al., International Current Pharmaceutical Journal, January 2016, 5(2): 14-21
24. Riazur Rehman et.al, ingiber officinale Roscoe (pharmacological activity), Journal of Medicinal Plants Research Vol. 5(3), 2011, pp. 344-348
25. Mascolo N, Jain R, Jain SC, Capasso F, Ethnopharmacologic investigation of ginger (Zingiber officinale). J. Ethnopharmacol., 1989, 27: 129-140
26. Chen CY, Li W, Qu KP, Chen CR (2013) Piperine exerts anti-seizure effects via the TRPV1 receptor in mice. See comment in PubMed Commons below Eur J Pharmacol 714: 288-294.

27. Bukhari IA, Pivac N, Alhumayyd MS, Mahesar AL, Gilani AH (2013) The analgesic and anticonvulsant effects of piperine in mice. See comment in PubMed Commons below J PhysiolPharmacol 64: 789-794.
28. Ajeet Singh et.al, Critical Review on Various Ethonomedicinal and Pharmacological Aspects of Piper longum Linn. (LONG PEPPER or PIPPALI), 6 (01), 2018, 48-60 DOI: 10.21276/IJIPSR.2018.06.01.253
29. Rabia Shabir Ahmad et.al, Biochemistry, Safety, Pharmacological Activities, and Clinical Applications of Turmeric: A Mechanistic Review, Evidence-Based Complementary and Alternative Medicine, Volume 2020, Article ID 7656919, 14 pages https://doi.org/10.1155/2020/7656919
30. Chander V, Aswal JS, Dobhal R, Uniyal DP. A review on Pharmacological potential of Berberine; an active component of Himalayan Berberis aristata. J Phytopharmacol 2017;6(1):53-58.
31. Roshy Joseph et.al., Therapeutic Potentials of Kantakari (Solanum xanthocarpum Schrad. & Wendl.), yurpharm Int J Ayur Alli Sci., Vol.1, No.2 (2012) Pages 46-53
32. Shashikant M Prajapati et.al., Phyto-Pharmacological Perspective of Yashtimadhu (Glycyrrhiza Glabra LINN.) – A Review, nternational Journal of Pharmaceutical & Biological Archives 2013; 4(5): 833 – 841
33. Kaur Barinder et.al., A review on gall karkatshringi, Journal of Medicinal Plants Research, Vol. 9(21), pp. 636-640, 3 June, 2015 DOI: 10.5897/JMPR2014. 5404
34. Goel B., Pathak N. Clinical evaluation of analgesic activity of Guduchi, Tinospora cordifolia using animal model. Journal of Clinical Diagnosis & Research 2014; 8: 1-4
35. Gupta MS, Sharma GD, Chakraborty B. Effect of aqueous extract of Tinospora cordifolia on functions of peritoneal macrophages isolated from CCl4 intoxicated male albino mice. BMC Complementary & Alternate Medicine 2011; 119102
36. Patgiri B., Umretia BL., Prajapati PK., Shukla VJ. Anti-inflammatory activity of aqueous extract of Tinospora cordifolia. Ayurveda 2014; 35: 108-10
37. Stance MH., A Nagy A., Tosa M., Vlad L. Hepatoprotective effect of orally administered melatonin & Tinospora cordifolia in experimental jaundice. Chirurgia (bucur) 2011; 106(2), 205-10.
38. Komala.A et.al, Ghrita as Ajasrika Rasayana, Unique Journal of Ayurvedic and Herbal Medicines, 2015, 03 (04): Page 61-63
39. Imam H, Zarnigar, Sofi G, Seikh A, Lone A. The incredible benefits of Nagarmotha (Cyperus rotundus). Int J Nutr Pharmacol Neurol Dis 2014;4:23-7
40. Priyanka K. Tayade et.al., Medicinal Uses and Pharmacological Activities of Parpatak (Fumaria parviflora lam.)-A Review, World Journal of Pharmaceutical Research, Volume 8, Issue 6, 337-344, DOI: 10.20959/wjpr20196-14793
41. Awanish Pandey et.al., Therapeutic Potential of Ushir [Vetiveria zizaniodes (Linn.) Nash]: Review Study, International Journal of Science and Research, Volume 8 Issue 6, June 2019, p. 1515-1519
42. Rakesh Kumar et.al., Phytochemistry and Pharmacology of Santalum album: A Review, World Journal of Pharmaceutical Research, Volume 4, Issue 10, 1842-1876
43. Haque MH, Haque AU, Use of sandalwood oil for the prevention and treatment of warts, skin blemishes and other viral-induced tumors. 2000, US Patent 470 6132756. 134.
44. Haque MH, Haque AU, Use of α- and β-santalols, major constituents of sandalwood oil, in the treatment of warts, skin blemishes and other viral- induced tumors. 2002; US Patent 6406706.
45. Chattopadhyay D, Sarkar MC, Chatterjee T, Sharma Dey R, Bag P, Chakraborti S, Khan MT, Recent advancements for the evaluation of anti-viral activities of natural products. New Biotechnology, 2009, 25, 347-368.
46. Desai VB, Hirenath RD, Pharmacological Screening of HESP and Sandalwood oil. Indian Perfumer, 1991; 35: 69-70.
47. Sharma J.P et.al., (2010). Herbal medicine as antipyretic: A comprehensive review. Int J Pharm Life Sci 1:18-22
48. Kashima, Y., Nakaya, S. and Miyazawa, M. (2014). Volatile composition and sensory properties of Indian herbal medicine-Pavonia odorata used in Ayurveda. J Oleo Sci 63:149-58

9) **Details of financial burden involved and how it will be met:**

Sr. No.	Expenditure head	Amount in Rupees
1	Raw Drugs (Medicine)	500000

2	Preparation of Medicines	200000
3	Remuneration	100000
4	Stationary	30000
5	Contingency	35000
6	Printing	50000
7	Travelling	35000
8	Liability Insurance	50000
	Total	10,00,000

The financial support will be provided by the Ministry of AYUSH, Government of India, New Delhi under the Extra Mural Research Scheme.

10) **Whether the research project is sponsored**: YES
Sponsoring authority: Ministry of AYUSH, Government of India, New Delhi

11) Any other relevant information: Attached herewith is Detail Research Protocol

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.
(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) Newspaper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Milind B. Nikumbh hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee. I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study

Kindly do the needful.

Dr. Milind. B. Nikumbh
Dean
Government Ayurved College,
Jalgaon

Dr. Milind B. Nikumbh
Dean, Govt. Ayurved College
Jalgaon

Government Ayurved College • Jalgaon •

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

Institutional Ethics Committee (IEC) Report

OutwardNo.:IEC / DUPMCH / 05 / 20

Date:23.09.2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled **"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"**

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) IEC, DUPMCH, was held on 23/09/2020 at (time) 3 PM in the (Venue) DUPMC, JALGAON with DR. RAVINDRAKUMAR BAKAL as Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
1.	Dr. Ravindrakumar. L. Bakal	Chairman	Principal	M pharm PHD
2.	Dr. Devendra R. Chaudhari	Member Secretary	Prof. & head	MD
3.	Dr. (Mrs) Maya N. Arvikar	Member	Prof. & head	MD
4	Dr. Nilesh Bendale	Member	Associate prof	MD
5	Adv. Satish Gadge	Member	Legal advisor	LLM
6	Dr. Prashant S. Warke	Member	Principal MBA	MBA, PhD

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

Institutional Ethics Committee (IEC) Report

OutwardNo.:IEC / DUPMCH / 05 / 20

Date:23.09.2020

Dr Milind B. Nikumbh
Dean,
Government Ayurved College& Hospital,
Jalgaon

Reference: The Research project entitled **"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"**

Dear Researcher,

The meeting of the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC) IEC, DUPMCH, was held on 23/09/2020 at (time) 3 PM in the (Venue) DUPMC, JALGAON with DR. RAVINDRAKUMAR BAKAL as Chairperson.

The following members attended the meeting.

Sr. No.	Name	Position on IRB/IEC	Designation and Affiliation	Qualification
1.	Dr. Ravindrakumar. L. Bakal	Chairman	Principal	M pharm PHD
2.	Dr. Devendra R. Chaudhari	Member Secretary	Prof. & head	MD
3.	Dr. (Mrs) Maya N. Arvikar	Member	Prof. & head	MD
4	Dr. Nilesh Bendale	Member	Associate prof	MD
5	Adv. Satish Gadge	Member	Legal advisor	LLM
6	Dr. Prashant S. Warke	Member	Principal MBA	MBA, PhD

It is hereby confirmed that, neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.
The IRB/IEC has reviewed and approved the following documents submitted for the above- mentioned Researchproject.

1. Research Proposal.
2. Consent form
3. Case Record Form

The IRB/IEC approves the project entitled **A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study**

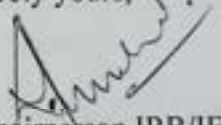
It is understood that the research project will be conducted under your direction, in a total of 380 (190 each in two groups) research participants, at Department of ***Government Ayurved College& Hospital, Jalgaon*** (Institute) as per the submitted protocol.

This approval is valid for the entire duration of the project. It is the policy of IRB/IEC that it be informed about any serious adverse event (SAE) occurring during the course of the research project within seven working days of the occurrence of the adverse event; It 'Death' is a SAE, it should be reported to the IRB/IEC within 24 hours of its occurrence via an e-mail.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IRB/IEC of an appropriate amendment. The IRB/IEC expects that the investigator should promptly report to the IRB/IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

The EC functions in accordance with ICH GCP and ICMR guidelines.

Sincerely yours,



Member Secretary/Chairperson IRB/IEC
(Signed and dated by the
IRB/IEC
Chairperson or Member Secretary)

Date of approval of the Research project:

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-23/09/2020

TO WHOM SO EVER IT MAY CONCERN

CONSENT LETTER

We have no objection to conduct clinical trials of the trial drugs under the studytitled **"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"** on COVID patients admitted in ourcentre for the purpose of research sponsored by Ministry of AYUSH, Government of India, under Extra Mural Research.

The investigators will have full access to the patients in our centre for examination of the patientunder the trial in the proposed study.

We hereby give consent to **Dr. Milind B. Nikumbh, Dean, Government Ayurved College& Hospital, Jalgaon,**the PrincipalInvestigator of the Research project titled**"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"** for the same.

In-charge
COVID Hospital/ Center
Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Confidential and Restricted Circulation
Among identified experts

"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"

Clinical Research Proposal

Submitted to The Ministry of AYUSH, Government of India, New Delhi

Principal Investigator	Co-investigator	AYUSH Associate
Dr. Milind B. Nikumbh Dean, Government Ayurved College, Jalgaon	Dr. Sandeep V. Binorkar, Assistant Professor, Government Ayurved College, Jalgaon	Dr. Leena Badgujar, MO, NRHM, AYUSH, Jalgaon Dr. Subhash Wadodkar Dr. Narendra Gujarati Ayurved Practitioners, Jalgaon

"A Clinical Evaluation of Efficacy of Ayurvedic treatment regimen as an Add-on therapy with Modern Medicine in COVID 19 - A Randomized, Multi-center, Single Blind, Prospective Clinical Study"

Background:

Corona virus disease 2019 is an ongoing pandemic disease, abbreviated as COVID 19, causes by newly identified sever acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The outbreak of this virus was primarily reported in Wuhan, China in December 2019 [1] and on 30th of January 2020 World Health Organization declared the to be Public Health Emergency of International Concerned and labeled it as Pandemic on 11th March 2020. [2,3] This condition, in general is characterized by fever, dry cough, fatigue and headache.

In a very short period of just four months, this disease has tolled approximately 3 million cases with more than 206000 deaths and have been reported in 185 countries. [4] In India, the first COVID 19 case was identified on 30th January 2020 in Kerala and by the end of April 2020, 27892 cases are confirmed with death of 872 infected patients.[5]

This viral pandemic has caused severe global socioeconomic disruption [6] having the potential equivalent to that of 'The Great Depression 'that occurred in 1930's. [7] This socioeconomic disruption has affected both poor and rich countries and had adversely affected personal income, tax revenue, large and small-scale industries, infrastructure and development field, education system, entertainment and agriculture industry.

As far as treatment is concerned, till date no specific antiviral agent is approved for COVID-19. Over the counter preparations for common cold, fluid intake and rest have shown to alleviate the symptoms. Depending upon the severity, oxygen supplement, breathing support or ventilation, intravenous fluids and usage of various pharmacological agents as per the requirement are the only available options left with the physicians and intensivist treating COVID-19 patients.

Considering the magnitude of this pandemic it is the need of the hour to develop a standardize approach and remedy for COVID-19. In Ayurveda, although no specific condition is described having exact resemblance with COVID-19 but few diseases have a comparable presentation with the same. Hypothetically it can be stated that, a good number of

classical drug preparations can be used against the COVID-19. In current clinical trials, a specially designed drug regime based on classical Ayurvedic text have been proposed depending on the present clinical presentation of COVID-19. All these classical presentations are used by Ayurvedic physicians since ages and have shown very promising results in various conditions resembling with the signs and symptoms of COVID-19.

METHODS

It is known fact under the Drugs and Cosmetics Rules of 1945, that there is no regulatory provision for clinical trials in alternative medicine. Therefore, the clinical research in Ayurveda should also be conducted as per AYUSH guidelines and clinical research or ICMR guidelines. Consequently, after acquiring the approval by the scientific advisory bodies and Institutional Ethics Committee, the research protocol will also be registered with the CTRI, the Clinical Trials Registry of India. [8]

Study Type	: Interventional
Purpose	: Treatment
Masking	: Nil
Control	: Controlled
Timing	: Prospective
No. of Groups	: Two

Number of Patients to be completed in the clinical trial (Sample Size) : 380 (190 Patients in each group) The total active cases all over India on 27th April 2020 are around 27,000. Considering this as a population, the sample size for the present research can be calculated as 380 using Raosoft® online sample size calculator [9] with 5% margin of error and 95% confidence level.

Groups: -

The subjects will be divided randomly in two groups (190 Patients in each group), viz. Trial and Control. The Trial group (Group -1) will be administered with Ayurvedic treatment regimen for COVID-19 along with the standard modern medicines and control group (Group-2) will be provided with the standard treatment protocol only which is followed in the modern medical hospitals.



TIMELINES:

- **Study duration** : 3 months
- **Pre-trial preparation & medicine procurement** : 15 days
- **Duration of intervention** : 15 days
- **Follow-up** : 30^{th} and 45^{th} day
- **Statistical analysis** : 1 month

Inclusion criteria:

1. All hospitalized cases above 18 years of age, clinically diagnosed with corona virus disease 2019 and presenting with mild to moderate signs and symptoms of COVID-19, quarantined at identified hospital set up.
2. Participants who can take medicines orally.
3. Patients willing to provide signed informed consent.

Exclusion criteria:

1. Cases of severe vomiting which would affect oral administration of medicine difficult.
2. Cases of respiratory failure and requiring mechanical ventilation.
3. Combined organ failure requiring ICU monitoring.
4. Pregnant and lactating women.
5. Subjects having an active malignancy.
6. Subjects giving history of significant cardiovascular event < 12 weeks prior to randomization.
7. Subjects having a chronic, contagious infectious disease, such as active tuberculosis, Hepatitis B or C, or HIV.
8. Subjects having active metabolic or gastrointestinal diseases that may interfere with nutrient absorption, metabolism, or excretion, excluding diabetes
9. Any other condition, which as per the investigator would jeopardize the outcome of the trial.

Withdrawal Criteria

a) The participant may be withdrawn from the trial if there is

- Any major ailment which necessitating the institution of new modalities of treatment.

OR

- Non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

b) Such cases will be immediately referred to the appropriate health authorities for further management.

**The decision to withdraw a participant from the trial would be taken only by the Principal Investigator, who will then have to set out a detailed justification and also indicate the line of further management-if needed. The same needs to be informed to the Sponsor and the Ethics Committee within two working days.

Interventions

Group I: (Ayurveda as add-on to standard care as per guidelines)

Name of the drug	Particulars	Details
Bilwadi Yog [10] (Ashtang Hridya Uttara tantra/35)	**Dose**	1 gm B.I.D.
	Dosage form	Tablet
	Route of Administration	Oral
	Time of Administration	After food
	Anupana	Shadangodak
	Duration of therapy	15 days
Kantakaryavaleha [11] Sharangdhar Samhita Madhyama khanda, 8; 5-8	**Dose**	3 gm B.I.D.
	Dosage form	Avaleha
	Route of Administration	Oral
	Time of Administration	Before food
	Anupana	Shadangodak
	Duration of therapy	15 days
Shadangodak [12] Charaka Samhita Chikitsa Sthana 1/15	**Dose**	40 ml B.I.D.
	Dosage form	Phant
	Route of Administration	Oral
	Time of Administration	As Anupana with other medicine
	Anupana	--
	Duration of therapy	15 days

Group-II: Conventional standard therapy

Authentication and Standardization of Research Medicines:

Raw drugs procured from the market will be authenticated by the experts from the Department of Dravyaguna and Rasashastra be authenticated as per the guidelines of the

Ayurvedic Pharmacopoeia of India (API) and compound formulation, will be prepared and standardized as per the guidelines of Ayurvedic Formulary of India (AFI).

RATIONALE BEHIND THE SELECTION OF DRUGS:

The proposed treatment module was selected on the basis of the classical references and indications of the selected drugs and also from the previous research studies published on these individual drugs suggesting its anti-viral, anti-pyretic, anti-bacterial, respiratory rejuvenator, Rasayan effects and immunomodulatory activities. [13-48]

OBJECTIVES

Primary Objectives:

- To assess the efficacy of Ayurvedic treatment regimen in the patients of positive coronavirus Disease. (Laboratory confirmation + Patients with uncomplicated respiratory tract infection which may have non-specific symptoms such as fever, fatigue, cough, anorexia, malaise, muscle pain, sore throat, dyspnoea, nasal congestion, or headache)

Secondary Objectives

- To assess the clinical safety of Ayurvedic treatment regimen in the patients of positive coronavirus Disease.

OUTCOMES

Primary Outcome Measure

1. Clinical cure rate: Time to negative conversion of severe acute respiratory syndrome corona-virus 2 (defined as viral load of respiratory specimen negative for two consecutive times when tested in an interval of two days)

Secondary Outcome Measures:

1. Length of stay in hospital
2. Duration of fever and respiratory symptoms
3. Improvement in hematological and laboratory parameters (Hs-CRP, ESR, TC, DC, Absolute lymphocyte count, LFT, RFT, IL-6, Ig E, Ig-G,Ig-M, LDH, Creatine Kinase, Platelet count),
4. Frequency of ADR/AE
5. Number of cases that required oxygen therapy during the intervention.

Method of Randomization: Subjects will be randomized into either the interventional drug group or placebo using a computer-generated table.

OBSERVATIONS: -

Observations will be taken on daily basis until the day of discharge.

Grading of Signs and Symptoms: -

1. Temperature: - Temperature will be recorded by means of Infrared thermometer (Temperature Gun).
2. Cough: - Cough will be graded by using Cough Severity Score and Frequency Score. Cough Severity Score will be obtained by using visual analog scale and cough frequency score will be graded as follows: -

Grade	Sign
0	No Cough at all
1	Occasional Hems
2	Mild isolated cough without associated or additional symptoms.
3	Moderate paroxysmal cough with additional symptoms.
4	Sever strenuous cough accompanied by chest discomfort.

3. Shortness of Breath: - SOB will be graded by using Five-point Likert scale: -

Grades	Signs
1	Not Short of breath
2	Mildly short of breath
3	Moderately short of breath
4	Severely short of breath
5	Severely short of breath requiring external assistance.

4. Headache: - Headache will be graded by using Visual Analog Scale.
5. Sore Throat: - This will be graded by using Visual Analog Scale.
6. Hemoptysis: -

Grade	Sign
Mild	< 50ml
Moderate	50 to 200 ml
Severe	>200ml
Massive	>600ml

SAFETY RECORDING

a. Adverse Events

All adverse events observed or reported by patients will be recorded in the CRF with information about severity (i.e., whether mild, moderate or severe) and possible relation to the study medication. Any serious adverse effects will be notified immediately to the study monitor. Such cases will be immediately referred to the appropriate health authorities for further management.

b. Clinical Laboratory Parameters

The following laboratory tests will be performed as per the study schedule.

The laboratory tests include:

Hs-CRP, ESR, TC, DC, Absolute lymphocyte count, LFT, RFT, IL-6, Ig E, Ig-G, Ig-M, LDH, Creatine Kinase, Platelet count). The laboratory test results will be recorded in CRF.

STATISTICAL METHODS

Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to Univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods.

DEVIATION FROM THE PROTOCOL:

The trial will be conducted in compliance with the protocol. Deviations from the protocol will not be made except when necessary to alleviate an immediate hazard to trial patients. All the deviations from the protocol, including unplanned changes to interventions, examinations, data collection and method of analysis will always be reported to sponsors and IEC at the earliest along with the exact reason for that deviation.

ADVERSE EVENTS

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

ADVERSE DRUG REACTION (ADR)

Any adverse event, if observed during treatment period or during follow up visits characterized by the suspicion of a causal relationship between the drug and the occurrence, i.e. judged as being at least possibly related to treatment will be clearly documented and its appropriate and timely management will be done. Such cases will be immediately referred to the appropriate health authorities for further management. The Principal Investigator will report the same to the Ethics committee and the sponsor(s) at the earliest.

DRUG COMPLIANCE

If there is more than or equal to 80% compliance, the participant would be continued in the trial. The compliance will be assessed at each follow-up by investigator on the admitted patients.

CONCOMITANT MEDICATION

Participants registered under the trial will be issued treatment cards with the entire treatment regimen written on it. They will be instructed to avoid the use of any other drugs on their own for any ailment and will be clearly instructed to consult the treating Investigating physician

for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he / she may prescribe to alleviate their ailments.

RESCUE MEDICATION

To alleviate any emergency and to relieve symptoms immediately, the use of rescue medication is permitted as per the wisdom / discretion of the Principal Investigator. However, the same will be documented in appropriate column in the Case Record Form.

DROP-OUTS

An attempt shall be made to record the reason for drop outs, if any during the clinical trial.

ETHICS

The trial will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian / ICH Good Clinical Practice (GCP) guidelines.

INSTITUTIONAL ETHICS COMMITTEE:

Institutional Ethics Committee (IEC) Scientific advisory committee approval is already procured from the Institutional Ethics Committee (IEC) of Government Medical College, Jalgaon. (IEC Approval No. 3536/20 dt. 29.04.2020 – Annexure-1) The research will also be registered to Clinical Trial Registry of India after the final approval for the EMR from Ministry of AYUSH and CCRAS.

PATIENT INFORMATION AND CONSENT FORM:

Written informed consent will be obtained from the subjects before the actual allocations in the study. Those who are not willing to participate in the study will be referred to appropriate health authorities for further treatment. The consent will be procured in the vernacular language. The format of the consent is attached herewith the proposal. (Annexure -2)

DATA DOCUMENTATION AND ANALYSIS

Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods. All information regarding clinical trial should be properly documented, carefully handled and meticulously stored in order to ensure its accurate interpretation and verification.

Study Schedule

Particular	Screening (Before Intervention)	Day 1	Day 7	Day 15	Day 30	Day 45
Informed consent & PIS	Y	--	--	--	--	--
Medical history	Y	--	--	--	--	--

for any symptom or complaint, or if they feel anything unusual. The Investigating physician will record any medication(s) he / she may prescribe to alleviate their ailments.

RESCUE MEDICATION

To alleviate any emergency and to relieve symptoms immediately, the use of rescue medication is permitted as per the wisdom / discretion of the Principal Investigator. However, the same will be documented in appropriate column in the Case Record Form.

DROP-OUTS

An attempt shall be made to record the reason for drop outs, if any during the clinical trial.

ETHICS

The trial will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian / ICH Good Clinical Practice (GCP) guidelines.

INSTITUTIONAL ETHICS COMMITTEE:

Institutional Ethics Committee (IEC) Scientific advisory committee approval is already procured from the Institutional Ethics Committee (IEC) of Government Medical College, Jalgaon. (IEC Approval No. 3536/20 dt. 29.04.2020 – Annexure-1) The research will also be registered to Clinical Trial Registry of India after the final approval for the EMR from Ministry of AYUSH and CCRAS.

PATIENT INFORMATION AND CONSENT FORM:

Written informed consent will be obtained from the subjects before the actual allocations in the study. Those who are not willing to participate in the study will be referred to appropriate health authorities for further treatment. The consent will be procured in the vernacular language. The format of the consent is attached herewith the proposal. (Annexure -2)

DATA DOCUMENTATION AND ANALYSIS

Clinical symptoms, Subjective parameters and Laboratory parameters will be subjected to univariate and multivariate analysis using Statistical Package for Social Sciences (SPSS) 15.0 version with appropriate statistical methods. All information regarding clinical trial should be properly documented, carefully handled and meticulously stored in order to ensure its accurate interpretation and verification.

Study Schedule

Particular	Screening (Before Intervention)	Day 1	Day 7	Day 15	Day 30	Day 45
Informed consent & PIS	Y	--	--	--	--	--
Medical history	Y	--	--	--	--	--

Laboratory Investigations	Y	--	--	Y	--	--
Chest Xray	Y	--	--	Y	--	--
Clinical Examination	Y	Y	Y	Y	Y	Y
Concomitant Medication	--	Y	Y	Y	--	--
Assessment of ADRs	--	Y	Y	Y	Y	Y
Assessment of Medication compliance	--	Y	Y	Y	Y	Y
Temperature Chart/Blood Gas analysis	Daily thrice					

Laboratory Examination:

- **Hematology**
  - Haemoglobin : _____ g/dl
  - T.L.C.: _____ / cu.mm.
  - D.L.C. : N ____ % E ____ % B ____ % L ____ % M _____ %
  - Absolute lymphocyte count _____
  - E.S.R.: _____ mm (at the end of 1st hour)
  - Blood Sugar: Fasting _____ mg%
  - HbA1c: _____ %
- **Bio-chemistry:**
  - Blood Urea: _____ mg/dL
  - Serum Uric Acid: _____ mg/dl.
  - Serum Creatinine: _____ mg/dL
  - S.G.O.T.(A.S.T.): _____ IU/L
  - S.G.P.T. (A.L.T.): _____ IU/L
  - Total protein: _____ gm/dl
  - S.Albumin: _____ gm/dl
  - S.Globulin: _____ gm/dl
  - A/G ratio: _____
  - Serum Bilirubin:
    - Conjugated bilirubin _____ mg/dl
    - Unconjugated bilirubin _____ mg/dl
  - Serum Alkaline Phosphatase: _____ IU/L
  - Hs-CRP
  - IL-6
  - Ig E
  - Ig-G
  - Ig-M
  - LDH,
  - Creatine Kinase
- Chest X-Ray-PA view _____
- USG-whole abdomen _____
- Blood gas analysis [pH (normal range 7.35-7.45), PCO2 (kPa, normal range 4.65-6.0), PO2 (kPa, normal range 10.6-13.3)]

Budget

The expenses associated with the proposal of the research project submitted herewith would be approximately Rs. 10,00,000 (Rupees Ten Lakh only). The details of expenditure head and the amount required to respective head is provided in the table below.

Sr. No.	Expenditure head	Amount in Rupees
1	Raw Drugs (Medicine)	500000
2	Preparation of Medicines	200000
3	Remuneration	100000
4	Stationary	30000
5	Contingency	35000
6	Printing	50000
7	Travelling	35000
8	Liability Insurance	50000
	Total	10,00,000

REFERENCES

1. "WHO Director- General's opening remarks at the media briefing on COVID-19, 11th March 2020
2. "Statement on the second meeting of the International Health Regulation (2005) Emergency Committee regarding the outbreak of Novel Corona Virus (2019-nCoV)" World Health Organization.
3. "WHO Director- General's opening remarks at the media briefing on COVID-19, 11th March 2020
4. "COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)" ArcGIS Johns Hopkins University
5. www.who.int/emergencies/diseases/novel-coronavirus-2019 (Accessed on 27.04.2020)
6. "Here Comes the Corona Virus Pandemic: Now, after many fire drills, the world may be facing a real fire". Editorial New York Times 29th Feb 2020
7. IMF Blog. "The great lockdown: Worst Economic downturn since the Great Depression." IMF Blog.
8. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf (Accessed on 27.04.2020)
9. http://www.raosoft.com/samplesize.html(Accessedon 27.04.2020)
10. Vagbhata - Ashtang Hridaya – Sarvaangasundara and Ayurveda Rasaayana, Collated by Anna Moreshwara Kunte, 9th Edition Chaukhamba Orientalia Publication, Varanasi. 2002
11. Sharangdhar Samhita, Englsih Translation by Shrikanthamurthy, 4th Edn, Chaukhambha Orientalia, Varanasi, 2001
12. Charak Samhita Vidyothini hindi commentary by Satya Narayan Shastri, Chaukhambha bharati academy Varansi Edition2001
13. Shahedur Rahman1,* and Rashida Parvin2 Therapeutic potential of Aegle marmelos (L.)-An overview, Asian Pac J Trop Dis. 2014 Feb; 4(1): 71–77. doi: 10.1016/S2222-1808(14)60318-2
14. Azad Rajaram et.al, Anti-inflammatory profiilr of (L) Correa (Bilwa) with special reference to young roots growing in different parts of India, Journal of Ayurveda and integrative medicine, 9(2):2018, p.90-98
15. Marc Maurice cohen, Tulsi- Ocimum sanctum: A Herb for all reasons, Journal of Ayurveda and integrative medicine, 5(4):2014, p.251-259
16. K Srinivasan et.al, Antinociceptive and Antipyretic Activities of Pongamia Pinnata Leaves, Phytother Res. 2003 Mar;17(3):259-64. doi: 10.1002/ptr.1126.
17. Khuda F, Iqbal Z, Khan A, Zakiullah, Nasir F, Shah Y. Antiinflammatory activity of the topical preparation of Valeriana wallichii and Achyranthes aspera leaves. Pak J Pharm Sci 2013; 26(3):451-4.

18. Krishna Kumar Ganta et. al, Anti-HCV Activity from Semi-purified Methanolic Root Extracts of Valeriana Wallichii, Phytother Res. 2017 Mar;31(3):433-440. doi: 10.1002/ptr.5765. Epub 2017 Jan 12.
19. Amrendra KumarChaudhary et.al., Cedrus deodara (Roxb.) Loud.: A Review on its Ethnobotany, Phytochemical and Pharmacological Profile, Pharmacognosy Journal, 3(23):2011, 12-17
20. Christine Tara Peterson et.al., Therapeutic Uses of Triphala in Ayurvedic Medicine, The Journal of Alternative and Complementary Medicine Volume 23, Number 8, 2017, pp. 607–614. DOI: 10.1089/acm.2017.0083
21. Zhang XJ, He LJ, Lu Q, Li DY. Zhongguo Zhong Yao Za Zhi. 2016;41(4):619-623. doi:10.4268/cjcmm20160412
22. Gupta et. al., Molecular Biology and Pharmacognosy of Beneficial Plants, Lenin Media Private Limited, Delhi, India, 2017, p.52-64
23. Hasan et al., International Current Pharmaceutical Journal, January 2016, 5(2): 14-21
24. Riazur Rehman et.al, ingiber officinale Roscoe (pharmacological activity), Journal of Medicinal Plants Research Vol. 5(3), 2011, pp. 344-348
25. Mascolo N, Jain R, Jain SC, Capasso F, Ethnopharmacologic investigation of ginger (Zingiber officinale). J. Ethnopharmacol., 1989, 27: 129-140
26. Chen CY, Li W, Qu KP, Chen CR (2013) Piperine exerts anti-seizure effects via the TRPV1 receptor in mice. See comment in PubMed Commons below Eur J Pharmacol 714: 288-294.
27. Bukhari IA, Pivac N, Alhumayyd MS, Mahesar AL, Gilani AH (2013) The analgesic and anticonvulsant effects of piperine in mice. See comment in PubMed Commons below J PhysiolPharmacol 64: 789-794.
28. Ajeet Singh et.al, Critical Review on Various Ethonomedicinal and Pharmacological Aspects of Piper longum Linn. (LONG PEPPER or PIPPALI), 6 (01), 2018, 48-60 DOI: 10.21276/IJIPSR.2018.06.01.253
29. Rabia Shabir Ahmad et.al, Biochemistry, Safety, Pharmacological Activities, and Clinical Applications of Turmeric: A Mechanistic Review, Evidence-Based Complementary and Alternative Medicine, Volume 2020, Article ID 7656919, 14 pages https://doi.org/10.1155/2020/7656919
30. Chander V, Aswal JS, Dobhal R, Uniyal DP. A review on Pharmacological potential of Berberine; an active component of Himalayan Berberis aristata. J Phytopharmacol 2017;6(1):53-58.
31. Roshy Joseph et.al., Therapeutic Potentials of Kantakari (Solanum xanthocarpum Schrad. & Wendl.), yurpharm Int J Ayur Alli Sci., Vol.1, No.2 (2012) Pages 46-53
32. Shashikant M Prajapati et.al., Phyto-Pharmacological Perspective of Yashtimadhu (Glycyrrhiza Glabra LINN.) – A Review, nternational Journal of Pharmaceutical & Biological Archives 2013; 4(5): 833 – 841
33. Kaur Barinder et.al., A review on gall karkatshringi, Journal of Medicinal Plants Research, Vol. 9(21), pp. 636-640, 3 June, 2015 DOI: 10.5897/JMPR2014. 5404
34. Goel B., Pathak N. Clinical evaluation of analgesic activity of Guduchi, Tinospora cordifolia using animal model. Journal of Clinical Diagnosis & Research 2014; 8: 1-4
35. Gupta MS, Sharma GD, Chakraborty B. Effect of aqueous extract of Tinospora cordifolia on functions of peritoneal macrophages isolated from CCl4 intoxicated male albino mice. BMC Complementary & Alternate Medicine 2011; 119102
36. Patgiri B., Umretia BL., Prajapati PK., Shukla VJ. Anti-inflammatory activity of aqueous extract of Tinospora cordifolia. Ayurveda 2014; 35: 108-10
37. Stance MH., A Nagy A., Tosa M., Vlad L. Hepatoprotective effect of orally administered melatonin & Tinospora cordifolia in experimental jaundice. Chirurgia (bucur) 2011; 106(2), 205-10.
38. Komala.A et.al, Ghrita as Ajasrika Rasayana, Unique Journal of Ayurvedic and Herbal Medicines, 2015, 03 (04): Page 61-63
39. Imam H, Zarnigar, Sofi G, Seikh A, Lone A. The incredible benefits of Nagarmotha (Cyperus rotundus). Int J Nutr Pharmacol Neurol Dis 2014;4:23-7
40. Priyanka K. Tayade et.al., Medicinal Uses and Pharmacological Activities of Parpatak (Fumaria parviflora lam.)-A Review, World Journal of Pharmaceutical Research, Volume 8, Issue 6, 337-344, DOI: 10.20959/wjpr20196-14793

41. Awanish Pandey et.al., Therapeutic Potential of Ushir [Vetiveria zizaniodes (Linn.) Nash]: Review Study, International Journal of Science and Research, Volume 8 Issue 6, June 2019, p. 1515-1519
42. Rakesh Kumar et.al., Phytochemistry and Pharmacology of Santalum album: A Review, World Journal of Pharmaceutical Research, Volume 4, Issue 10, 1842-1876
43. Haque MH, Haque AU, Use of sandalwood oil for the prevention and treatment of warts, skin blemishes and other viral-induced tumors. 2000, US Patent 470 6132756. 134.
44. Haque MH, Haque AU, Use of α- and β-santalols, major constituents of sandalwood oil, in the treatment of warts, skin blemishes and other viral- induced tumors. 2002; US Patent 6406706.
45. Chattopadhyay D, Sarkar MC, Chatterjee T, Sharma Dey R, Bag P, Chakraborti S, Khan MT, Recent advancements for the evaluation of anti-viral activities of natural products. New Biotechnology, 2009, 25, 347-368.
46. Desai VB, Hirenath RD, Pharmacological Screening of HESP and Sandalwood oil. Indian Perfumer, 1991; 35: 69-70.
47. Sharma J.P et.al., (2010). Herbal medicine as antipyretic: A comprehensive review. Int J Pharm Life Sci 1:18-22
48. Kashima, Y., Nakaya, S. and Miyazawa, M. (2014). Volatile composition and sensory properties of Indian herbal medicine-Pavonia odorata used in Ayurveda. J Oleo Sci 63:149-58

*****

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 23/10/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 24/10/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Ravindrakumar L.Bakal
2	Dr. D. R. Chaudhari
3	Dr. (Mrs) Maya N.Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr.Nilesh Bendale
7	Dr.Rahul P.Bhavasar
8	Adv. Satish Gadge
9	Dr. Prashant M. Warke
10	Mr. Prabhakar M. Jangale
11	Mr. Sandesh Y.Patil

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 06 / 2020/ Minutes of Meeting

DATE: 24/10/2020

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Ravindrakumar. L. Bakal	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Dr. Rahul Prakash Bhavasar	Member	
8.	Adv. Satish Gadge	Member	
9.	Dr. Prashant S. Warke	Member	
10.	Mr. Prabhakar. M. Jangale	Member	
11.	Mr. Sandesh Y. Patil	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

4.1 To discuss the research study of **MISS. DHARMISHTHA N. SONI** titled **"COVID - 19 IMPACT ON MENTAL HEALTH OF STUDENTS – MEDICAL AND NON MEDICAL – INDIAN SCENARIO."**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from October 2020 to December 2020 The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
COVID 19 Impact on Mental Health of students - Medical & Non Medical - Indian Scenario.

2. Name of the Principal Investigator/ Under/Post graduate student:
Miss Dharmishtha Soni
FINAL MBBS - I student.

3. Name of the co-investigator/ ~~UG/PG guide/Trial monitor~~ (if applicable)
Dr. Vaishali Nagose Rathod
(Dr. Vaishali Babkarao Nagose)
Asso. Prof. Pathology.

4. i) Signature of Principal investigator/ UG/PG student:
D. N. Soni

ii) Signature of co-investigator/ UG/PG guide/Trial monitor:
Nagose

iii) Signature of HOD of Principal Investigator/UG/PG student:
(with seal)

for. Upamale

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Recejpt by IEC (submissi-----on of application) _____
2) Date of resubmission to IEC _____
3) Date of IEC meeting _____
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: _____

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 months

7) Risk factor for the patient (give details): None.

A) ProceduraIL:

_____

B) Adverse drug reaction (ADRs):

C) Invasive investigations (if any):

D) Explain the measures to counter the above risk factors:

8) Details about research project – Synopsis attached.

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met: NIL

10) Whether the research project is sponsored: ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).

11) Any other relevant information:

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient Information sheet.

(b) Informed consent form for subject participating in clinical trial (In English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF) ✓
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

D.N. Soni

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Dharamishtha Soni hereby submitting synopsis of my research protocol/ ~~PG dissertation~~ for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
COVID-19 impact on Mental Health of students - Medical & Non Medical - Indian scenario.

Kindly do the needful.

D.N. Soni

(Candidate name and signature)
Dharamishtha Soni

Co-investigator/ ~~Guide~~ name and signature)
Dr. Vaishali Nagose Rathod

for. Ugamale

(HOD name and Signature with Dept. seal)
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 10/11/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 11/11/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 11/11/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To discuss the research study of **Dr. RANJANA C. SHINGNE, Associate Professor, Department of PHYSIOLOGY -**

"EFFECT OF E-LEARNING DURING COVID – 19 PANDEMIC ON UNDERGRADUATE MEDICAL STUDENTS."

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from DECEMBER 2021 to JANUARY 2022.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr. RAHUL PRAKASH BHAVASAR.
Member Secretary
DUPMCH

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Covering letter

Through Proper Channel Only

Date - 01/11/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. Ranjana C. Shingre hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Effect of lockdown on E-learning during COVID-19 Pandemic on undergraduate medical students

Kindly do the needful.

RA
Dr. Ranjana C. Shingre
(Principal Investigator name and signature)

Dr. Shivanand S Rathod
(HOD name and Signature with Dept. seal)

PROFESSOR & HOD
Dept. of Physiology
Dr. Ulhas Patil Medical Colleg
and Hospital, Jalgaon Kh.

(Guide name and signature)

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	**Title of the Research Project/ Dissertation** Effect of lockdown on E-learning during COVID-19 Pandemic on undergraduate medical Students	
		Signature
2.	**Name of the Principal Investigator/ Under/Post graduate student:** Dr. Ranjana C. Shingre	RCS
3.	**Name of the co-investigator/s (if applicable)** i) Santosh Kumar Jha ii) Shivanand S Rathod iii) iv)	Santosh Rathod
4.	**Name of UG/PG guide**	NO
5.	**Name of Trial monitor / co-guide**	NO
6.	**HOD of Principal Investigator/UG/PG student:**	(With seal) PROFESSOR & HOD Dept. of Physiology Dr.Ulhas Patil Medical Col and Hospital,Jalgaon K
7.	**HOD of other Departments involved**	(With seal) NO

8.	**Place where research work will be carried out**	
	a. At DUPMC&	Yes / No
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	**Time period required for completion of research project and it's analysis** (Approximately)	From –To (Date) Dec 2021 – Jan 2022
10.	**Risk factor for the patient** (give details): A) Procedural NA	
	B) Adverse drug reaction (ADRs) NA	
	C) Invasive investigations (if any) NA	
	D) Explain the measures to counter the above risk factors. NA	

11.	**Details about research project must include**	Yes	No
	(a) Project title	✓	
	(b) Aims and objectives:	✓	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	✓	
	(d) Materials and methods (Research plan and its implications)	✓	
	(e) Statistical analysis	✓	
	(f) Conflict of interest:	✓	
	(g) Risk factors:		✓
	(h) List of references:	✓	

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

12.	**Details of financial burden involved and how it will be met:** NO	
13.	**Whether the research project is sponsored:**	Yes / No
14.	**Sponsoring authority**: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	**Any other relevant information:** NO	

16. **Enclosures:**

		Attached	Not attached	Not applicable
1	Patient information sheet			✓
2	Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi)	✓		
3	Case Record Form (CRF)			✓
4	Undertaking by the investigator			
5	Stability testing of new drug			✓
6	Content of the proposed protocol for conducting clinical trial			✓
7	Data elements for reporting Serious ADR/ADE occurring in clinical trial.			✓
8	Study Flow Chart if any.			✓
9	Newspaper publication matter for subject recruitment if any.			✓
10	Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

RSA

Signature

Principal Investigator.

---

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

(For IEC Office use only)

1	Sr. No given to project	20
2	Department	Physiology
3	Date of Receipt by IEC (submission of application)	01/11/21
4	Date of resubmission to IEC	10/11/21
5	Date of IEC meeting	11/11/21
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	12/11/21

CHAIRPERSON
IEC, DUPMCH

MEMBER SECRETARY
IEC, DUPMCH

Research Protocol

Project Title- Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students.

Aims and Objectives –

1. To assess effectiveness of E-learning classes as compared to conventional classroom teaching-learning method.
2. To assess perceptions of medical students on the role of E-learning in facilitating medical education during COVID-19 pandemic.
3. To evaluated knowledge of erlectronic gadgets used during E-learning activities.

Introduction – COVID-19 viral infection started in December 2019, Wuhan, China and spread rapidly throughout the globe. As the infection spread throughout the world rapidly, on March 11, 2020 World Health Organization (WHO) declares it as pandemic [1]. As the infection spreads rapidly, government of India announces nation wise lockdown on 25th March 2020 for 21 days [2]. Pandemic imposed lockdown in all areas, including educational institutions. In the wake of institute shutdown, this was challenging time for professional education which combated through introduction of E-learning through online classes so as to ensure continuation of teaching -learning process for medical students. Our institute started online classes from 20th April 2020 and continued till the end of academic year. Again, we continued e-learning process ON and OFF as per the guidelines of government of India. We did E-learning total of 5 months i.e. from March 2021- July 2021. Present study is conducted to investigate perception of medical students on the role of online teaching in facilitating medical education during the COVID-19 pandemic.

Materials and Methods – This online study will be done on 1st year MBBS students (total of 150 students), who have already completed online classes from March 2021 to July 2021. A set of self-designed questionnaire will be given to assess the effectiveness of learning through online classes and their understanding with satisfaction level on various parameters.

Statistical Analysis – After completion of study, it will be analysed by using Students T-test.

Conflict of interest – None

References

1. WHO Director-General's opening remarks at the media briefing on COVID19 -March 2020

2. Newspaper- THE HINDU , March 25, 2020. https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-covid-19-toll-touches-10/article61958513.ece

Questionnaires

1. Are you willing to participate in this study?

   Yes / No

2. On which device you are attending online lectures?

   Smart phone/ Laptop /Tablets

3. Whether online teaching was good decision to continue your education during lockdown?

   a)Yes b) No c) Can not say

4. Does pandemic has increased your stress?

   a)Yes b) No c) Can not say

5. Are you feeling anxious during lock down?

   a) Yes b) No c) Can not say

6. Duration of screen use before pandemic COVID-19

   a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs

7. Duration of screen use during pandemic COVID-19

   a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs

8. Do you have technophobia before joining the online session?

   Yes / No

9. Do you like online teaching over classroom teaching?

   Yes / No

10. Do you like online exams?

    Yes / No

11. Do you like classroom exam?

Yes / No

12. Do you feel that pandemic has affected your academic performances?

Yes / No

13. Do you face internet error while connecting for online class?

a) Yes b) No c) Sometimes d) Never

14. Do you like open book exam?

Yes / No

15. Do you feel flexibility while attending online lecture?

Yes / No

16. Which type of online lecture is good - live or recorded?

17. Disturbances while attending online session

a) Yes b) No c) Sometimes d) Never

18. What will you prefer in future?

a) E-learning b) Class room teaching

19. To improve online lecture effectiveness any suggestion -

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

Dr. Ranjana C. Shingne
Dept. of Physiology, Dr. Vilas Patil Medical College and Hospital, Jalgaon Khurd, Jalgaon, Maharashtra, India

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

Dr. Vilas Patil Medical College and Hospital
Jalgaon Khurd, Jalgaon, Maharashtra, India

3. Name and address of all clinical laboratory facilities to be used in the study.

NA

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

IEC, DUPMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

Dr. Santosh Kumar Jha

Dr. Shivanand S Rathod

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students

7. Commitments:

   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.

   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment.

except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

PSA

01.11.24

8. Signature of Investigator with date.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Covering letter

Through Proper Channel Only

Date - 01/11/24

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. Ranjana C. Shingne ..... hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students

Kindly do the needful.

R&A
Dr. Ranjana C. Shingne
(Principal Investigator name and signature)

PROFESSOR & HOD
Dept. of Physiology
Dr. Ulhas Patil Medical College
and Hospital, Jalgaon Kh.

(Guide name and signature)

(HOD name and Signature with Dept. seal)
Dr. Shivanand S Rathod

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	**Title of the Research Project/ Dissertation** Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students	
		Signature
2.	**Name of the Principal Investigator/ Under/Post graduate student:** Dr. Ranjana C. Shirgre	R&A
3.	**Name of the co-investigator/s (if applicable)** i) Santosh Kumar Jha ii) Shivanand S Rathod iii) iv)	Santosh
4.	**Name of UG/PG guide**	NA
5.	**Name of Trial monitor / co-guide**	NA
6.	**HOD of Principal Investigator/UG/PG student:**	(With seal) PROFESSOR & HOD Dept. of Physiology Dr. Ulhas Patil Medical College and Hospital, Jalgaon Kh.
7.	**HOD of other Departments involved**	(With seal) NA

8.	**Place where research work will be carried out**	
	a. At DUPMC&	✓Yes / No
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	**Time period required for completion of research project and it's analysis** (Approximately)	From –To (Date) Dec 2021 – Jan 2022
10.	**Risk factor for the patient** (give details): A) Procedural NA	
	B) Adverse drug reaction (ADRs) NA	
	C) Invasive investigations (if any) NA	
	D) Explain the measures to counter the above risk factors. NA	

11.	**Details about research project must include**	Yes	No
	(a) Project title	✓	
	(b) Aims and objectives:	✓	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	✓	
	(d) Materials and methods (Research plan and its implications)	✓	
	(e) Statistical analysis	✓	
	(f) Conflict of interest:	✓	
	(g) Risk factors:		✓
	(h) List of references:	✓	

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

12.	**Details of financial burden involved and how it will be met:**	
13.	**Whether the research project is sponsored:**	Yes / No ✓
14.	**Sponsoring authority**: (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	**Any other relevant information:**	

16. **Enclosures:**

		Attached	Not attached	Not applicable
1	Patient information sheet			✓
2	Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi)	✓		
3	Case Record Form (CRF)			✓
4	Undertaking by the investigator			
5	Stability testing of new drug			✓
6	Content of the proposed protocol for conducting clinical trial			✓
7	Data elements for reporting Serious ADR/ADE occurring in clinical trial.			✓
8	Study Flow Chart if any.			✓
9	Newspaper publication matter for subject recruitment if any.			✓
10	Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

RA

Signature

Principal Investigator.

---

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

(For IEC Office use only)

1	Sr. No given to project	20
2	Department	Physiology
3	Date of Receipt by IEC (submission of application)	01/11/21
4	Date of resubmission to IEC	10/11/21
5	Date of IEC meeting	11/11/21
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	12/11/21

CHAIRPERSON
IEC, DUPMCH

MEMBER SECRETARY
IEC, DUPMCH

Research Protocol

Project Title- Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students.

Aims and Objectives –

1. To assess effectiveness of E-learning classes as compared to conventional classroom teaching-learning method.
2. To assess perceptions of medical students on the role of E-learning in facilitating medical education during COVID-19 pandemic.
3. To evaluated knowledge of erlectronic gadgets used during E-learning activities.

Introduction – COVID-19 viral infection started in December 2019, Wuhan, China and spread rapidly throughout the globe. As the infection spread throughout the world rapidly, on March 11, 2020 World Health Organization (WHO) declares it as pandemic [1]. As the infection spreads rapidly, government of India announces nation wise lockdown on 25th March 2020 for 21 days [2]. Pandemic imposed lockdown in all areas, including educational institutions. In the wake of institute shutdown, this was challenging time for professional education which combated through introduction of E-learning through online classes so as to ensure continuation of teaching -learning process for medical students. Our institute started online classes from 20th April 2020 and continued till the end of academic year. Again, we continued e-learning process ON and OFF as per the guidelines of government of India. We did E-learning total of 5 months i.e. from March 2021- July 2021. Present study is conducted to investigate perception of medical students on the role of online teaching in facilitating medical education during the COVID-19 pandemic.

Materials and Methods – This online study will be done on 1st year MBBS students (total of 150 students), who have already completed online classes from March 2021 to July 2021. A set of self-designed questionnaire will be given to assess the effectiveness of learning through online classes and their understanding with satisfaction level on various parameters.

Statistical Analysis – After completion of study, it will be analysed by using Students T-test.

Conflict of interest – None

References

1. WHO Director-General's opening remarks at the media briefing on COVID19 -March 2020
2. Newspaper- THE HINDU , March 25, 2020. https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-covid-19-toll-touches-10/article61958513.ece

Questionnaires

1. Are you willing to participate in this study?

   Yes / No

2. On which device you are attending online lectures?

   Smart phone/ Laptop /Tablets

3. Whether online teaching was good decision to continue your education during lockdown?

   a)Yes b) No c) Can not say

4. Does pandemic has increased your stress?

   a)Yes b) No c) Can not say

5. Are you feeling anxious during lock down?

   a) Yes b) No c) Can not say

6. Duration of screen use before pandemic COVID-19

   a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs

7. Duration of screen use during pandemic COVID-19

   a) < 2 hrs b) 2- 4 hrs c) 4-6 hrs d) >8 hrs

8. Do you have technophobia before joining the online session?

   Yes / No

9. Do you like online teaching over classroom teaching?

   Yes / No

10. Do you like online exams?

    Yes / No

11. Do you like classroom exam?

Yes / No

12. Do you feel that pandemic has affected your academic performances?

Yes / No

13. Do you face internet error while connecting for online class?

a) Yes b) No c) Sometimes d) Never

14. Do you like open book exam?

Yes / No

15. Do you feel flexibility while attending online lecture?

Yes / No

16. Which type of online lecture is good - live or recorded?

17. Disturbances while attending online session

a) Yes b) No c) Sometimes d) Never

18. What will you prefer in future?

a) E-learning b) Class room teaching

19. To improve online lecture effectiveness any suggestion -

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

Dr. Ranjana C Shingne
Dept. of Physiology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon Khurod, Jalgaon, Maharasthra, India

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

Dr. Ulhas Patil Medical College and Hospital
Jalgaon Khurod, Jalgaon, Maharasthra, India

3. Name and address of all clinical laboratory facilities to be used in the study.

NA

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

IEC, DUPMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

Dr. Santosh Kumar Jha
Dr. Shivanand S Rathod

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

Effect of lockdown on E-learning during COVID-19 pandemic on undergraduate medical students

7. Commitments:

   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment,

except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

DSA
01.11.21

8. Signature of Investigator with date.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2058557 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in
2366657

Date:- 30/09/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 04/10/20021 to 09/01/2021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 04/10/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P.B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of medicine PGs-

1	**Dr. KAMELI MOHAMMAD JUNAID RAFEEQUE AHMAD**	COMPARATIVE STUDY OF ECG AND CORONARY ANGIOGRAPHIC FINDINGS WITH ACUTE CORONARY SYNDROME IN DIABETIC AND NON-DIABETIC PATIENTS IN TERTIARY CARE CENTRE
2	**Dr. KOTECHA TEJAS KUNDAN**	STUDY OF CLINICAL PROFILE OF PATIENTS WITH HYPONATREMIA IN TERTIARY CARE HOSPITAL
3	**Dr. NANDEDKAR ADITYA MAHADEV**	THE STUDY OF SERUM MAGNESIUM AND VITAMIN D3 IN TYPE 2 DIABETES MELLITUS AND ITS CORRELATION WITH CORONARY ARTERY DISEASE
4	**Dr. PRIYANKA ASHOK BHALKE**	BACTERIAL SPECTRUM OF ASCITIC FLUID IN ALCOHOLIC LIVER DISEASE PATIENT ON ADMISSION AND ITS CORRELATION WITH SERUM ASCITIC ALBUMIN GRADIENT.
5	**Dr. WAGAJ SUSHANT PRAKASH**	A STUDY TO ESTIMATE PREVALENCE OF ANAEMIA IN ACUTE AND CHRONIC INFLAMMATION IN PATIENTS ATTENDING TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 05/10/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of Surgery PGs-

1	Dr. ANISH AVINASH JOSHI	COMPARATIVE STUDY OF EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA WITH SALINE DRESSING IN DIABETIC FOOT ULCER BY EXAMINING NEOVASCULARIZATION ON BIOPSY
2	Dr. FARKE VAIBHAV BALASAHEB	STUDY OF ETIOLOGY AND MANAGEMENT OF PERITONITIS AT TERTIARY CARE HOSPITAL
3	Dr. MANKAR SHUBHAM SHRIKRUSHNA	SPECTRUM OF DISEASES MANAGED BY LAPAROSCOPY AND ITS OUTCOME AT TERTIARY CARE CENTRE
4	Dr. SHRIYASH KONDIBA SONAWANE	STUDY OF MANAGEMENT AND OUTCOME OF ACUTE OBSTRUCTIVE UROPATHY DUE TO CALCULUS IN A TERTIARY CARE CENTRE
5	Dr. SIRPURAM VARUNDEV ASHOK	EFFECT OF FLAP FIXATION TECHNIQUE ON SEROMA FORMATION AND ITS COMPLICATIONS IN PATIENTS UNDERGOING BREAST CANCER SURGERY AT A TERTIARY CARE CENTER.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 06/10/2021
Location:
Dean's Office
Recorded By: Dr. RAHUL P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of Anesthesia and Pathology PGs-

1	Dr. DESHPANDE HARSHA SANJAY	TO STUDY THE EFFECT OF INTRAVENOUS MAGNESIUM SULPHATE IN ATTENUATING THE HEMODYNAMIC RESPONSE DURING LARYNGOSCOPY AND INTUBATION IN PATIENTS REQUIRING GENERAL ANAESTHESIA AT A TERTIARY CARE CENTRE.
2	Dr. KELGAONKAR VIJAYA VIVEK	A COMPARATIVE STUDY OF DEXAMETHASONE AS AN ADJUVANT TO LOCAL ANAESTHETIC DRUG FOR SUPRACLAVICULAR BLOCK WITH PLACEBO IN A TERTIARY CARE CENTER
3	Dr. PRAJAKTA PRAKASH SHILAHAR	COMPARATIVE STUDY BETWEEN FENTANYL AND BUPRENORPHINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRA UMBILICAL SURGERIES
4	Dr. SONONE SHIVAJI DILIP	TO COMPARE EFFECT OF 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB SURGERIES IN TERTIARY CARE CENTRE.
5	Dr. KAMBLE PRIYANKA SHASHIKANT	THE STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY OF HEAD AND NECK REGION LYMPHADENOPATHY WITH ITS HISTOPATHOLOGIC CORRELATION IN TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 07/10/2021
Location:
Dean's Office
Recorded By: Dr. RAHUL. P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of three OBGY and two Pediatrics PGs-

1	Dr. DONGARWAR AKASHKUMAR SHALIKRAM	AN OBSERVATIONAL STUDY OF INTRAOPERATIVE DIFFICULTIES IN REPEAT CAESAREAN SECTION COMING TO TERTIARY CARE HOSPITAL
2	Dr. MAHESH GAJANAN DESHMUKH	TRANSABDOMINAL ULTRASOUND ASSESSMENT OF FETAL OCCIPUT - SPINE ANGLE TO PREDICT THE MODE OF DELIVERY
3	Dr. YASHASHREE PRADIP DESHMUKH	A STUDY OF UTERINE ARTERY DOPPLER FOR PREDICTION OF PREECLAMPSIA FROM 12 TO26 WEEKS OF GESTATION IN TERTIARY CARE CENTER.
4	Dr. RANGNEKAR PRADNIL KISHOR	CLINICAL PROFILE OF LOW BIRTH WEIGHT NEONATES ADMITTED IN NICU AT TERTIARY CARE CENTER
5	Dr. SHUKLA SURUCHI RAMPRASAD	PROSPECTIVE STUDY OF CLINICAL OUTCOME OF EARLY DISCHARGED VERY LOW BIRTH WEIGHT BABIES FROM NICU AT WEIGHT BETWEEN 1300GMS TO 1800GMS.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 08/10/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P.B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study of three Ophthalmology and two ENT PGs-

1	Dr. AKASH UTTAMRAO MALVI	A STUDY TO EVALUATE AND COMPARE VISUAL OUTCOMES AFTER CATARACT SURGERY IN DIABETICS COMPARED TO NONDIABETIC PATIENTS AT A TERTIARY CARE CENTRE.
2	Dr. ANUJA VINAYAK GADGIL	A CLINICAL STUDY OF SUTURELESS GLUEFREE CONJUNCTIVAL AUTOGRAFT REPAIR IN PTERYGIUM SURGERY.
3	Dr. DESHMUKH KALPANA ARJUNRAO	STUDY OF EFFECT OF MYOPIA AND AXIAL LENGTH ON PERIPAPILLARY RETINAL NERVE FIBRE LAYER USING SPECTRAL DOMAIN OPTICAL COHERENT TOMOGRAPHY
4	Dr. HARSHAL VASUDEO MAHAJAN	A COMPARATIVE STUDY OF ENDOSCOPIC SEPTOPLASTY OVER CONVENTIONAL SEPTOPLASTY IN TERTIARY CARE CENTER.
5	Dr. KHANDAGALE SHRUTI SHAILENDRA	A COMPARATIVE STUDY BETWEEN GRAFTS OF TRAGAL CARTILAGE, TEMPORALIS FASCIA LATA IN PATIENTS POSTED FOR REVISION TYMPANOPLASTY.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 09/10/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P.B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the 6 monthly report of research study three Orthopedics, two Skin and one Chest and TB PGs-

1	DR. JANBANDHU RAHUL SHANTILAL	COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF FIXATION BY OPEN AND CLOSED METHODS IN DISTAL END RADIUS FRACTURE IN TERTIARY CARE HOSPITAL.
2	DR. PATIL PARIKSHIT PRATAP	TO STUDY FUNCTIONAL OUTCOME OF SURGICAL DECOMPRESSION IN LUMBAR SPINAL STENOSIS IN A RURAL HOSPITAL
3	DR. VELANKAR SUNEET NITIN	STUDY ON EFFICACY AND FUNCTIONAL OUTCOME OF AUTOLOGOUS PLATELET RICH PLASMA INJECTION IN ADHESIVE CAPSULITIS, LATERAL EPICONDYLITIS AND PLANTAR FASCIITIS.
4	DR. KALBANDE PRAJAKTA PRAKASH	STUDY OF VARIOUS CLINICAL PATTERNS OF ADVERSE CUTANEOUS DRUG REACTIONS AT DERMATOLOGY OUT PATIENT DEPARTMENT IN A TERTIARY CARE CENTRE
5	DR. SHAIKH MUBINA IRFAN	CLINICO EPIDEMIOLOGICAL STUDY OF HERPES ZOSTER AND POST HERPETIC NEURALGIA AND ITS IMPACT ON QUALITY OF LIFE
6	DR. SAMADHAN DATTATRAYA BAHEKAR	STUDY OF POST COVID 19 PULMONARY COMPLICATIONS AT A TERTIARY CARE CENTER - PROSPECTIVE OBSERVATIONAL STUDY.

Minutes of meeting:-

1. 6 monthly reports of all PGs were discussed.
2. Difficulties in conducting study were discussed and same time the query was solved with the help of PG guide.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in

Ref. No. IEC/GCON/2021/1

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Puja c. waghmare (Ms.Vishakha Ganvir)	Child Health Nursing.	Approved	"A study to assess the knowledge, attitude, anxiety and coping strategies of students (16 to 18 years) during COVID – 19 epidemic in selected urban area."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Puja C. Waghmare Dept. of Child Health Nursing.
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http: www.dupmc.ac.in/

Ref. No. IEC/GCON/2021/2

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	MS. Utkarsha Gawande (Mrs. Vishakha Ganvir)	Child Health Nursing	Approved	Study to assess the physical and psychological impact of lockdown during covid-19 pandemic on school age children, in view to develop the information booklet on how to mitigate its effect in selected urban area.

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Utkarsha Dhanraj Gawande Dept. of Child Health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Ref. No. IEC/GCON/2021/4

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Shital Umate (Mrs.Vishakha Ganvir)	Child Health Nursing	Approved	"A descriptive study to assess the attitude & behavioural changes in pimary school children regarding unplanned school closure during covid-19 pandemic in selected urban area."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Shital Umate Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in

Ref. No. IEC/GCON/2021/5

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Shilpa Vairagade (Mrs.Vishakha Ganvir)	Child Health Nursing	Approved	"Study to assess the challenges faced by village parents of primary school children regarding online education during lockdown in selected rural area ."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Shilpa Vairagade Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in

Ref. No. IEC/GCON/2021/6

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms.Kirti Patil (Mrs. Jacinth Dhaya)	Community health nursing	Approved	"A true experimental study to assess the effectiveness of kriya yoga in reduction of anxiety level among the nursing staff at selected COVID hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Kirti Patil Dept. Community health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Ref. No. IEC/GCON/2021/7

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Dipali Gote Mrs Manorama Kashyap)	Medical Surgical Nursing-(Neurosciences nursing)	Approved	"A study to assess the effectiveness of self instructional module on knowledge regarding prevention of early complication following stroke among staff nurses working at selected hospital."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms Dipali Gote Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in

Ref. No. IEC/GCON/2021/8

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms.Snehal Diwakar Kshirsagar (Mrs.Manorama Kashyap)	Medical Surgical Nursing-(Neurosciences nursing)	Approved	"A quasi experimental study to assess the effectiveness of Backward Walking Training to improve gait among stroke patient admitted at selected rehabilitation center."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms.Snehal Kshirsagar Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http: www.dupmc.ac.in

Ref. No. IEC/GCON/2021/9

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Mr.Chinmay Prakash Chopade (Mrs.Manorama Kashyap)	Medical Surgical Nursing-(Neurosciences nursing)	Approved	"A quasi experimental study to assess the effectiveness of structured teaching programme on knowledge regarding lumbar puncture, its complication and prevention of complication among staff nurses working at selected hospital."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Mr. Chinmay Chopade Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http: www.dupmc.ac.in

Ref. No. IEC/GCON/2021/10

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 13/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Priti Gaikwad (Mrs.Manorama Kashyap)	Medical Surgical Nursing-(Neurosciences nursing)	Approved	"A pre experimental study to assess the effectiveness of video assisted teaching programme on knowledge regarding swallowing therapy for dysphagia in patient with stroke among staff nurses working at selected hospital "

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Priti Gaikwad Dept. Medical Surgical Nursing -(Neurosciences nursing)
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Ref. No. IEC/GCON/2021/11

Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Ms. Priyanka G. Gadekar) (Ms. Ashwini Vaidya)	Mental Health Nursing.	Approved	"A quasi experimental study to assess the effectiveness of self- instructional module on knowledge regarding management of client with mania among staff nurses at selected hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Ms. Priyanka G. Gadekar Dept., of Mental Health Nursing.
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Ref. No. IEC/GCON/2021/12 Date:19/07/2021

The Institutional Ethical Committee in its meeting held on 12/07/2021 has approved the following research work proposed to be carried out at Godavari College of Nursing, Jalgaon.

This approval has been granted on the assumption that, the proposed work will be carried out in accordance with IEC guidelines. The details on proposed research work approved by the committee are as under:-

Following **Msc 1st Year Nursing** Research Project were discussed and **given approval**.

Sr. No.	Chief investigator (Co-Investigator)	Department	Approval	Topic of proposed
01	Mr.Akshay Wankhede (Ms.Ashwini Vaidya)	Mental Health Nursing	Approved	"A Quasi-experimental study to assess the effectiveness of structured teaching programme on knowledge regarding prevention of complications of electroconvulsive therapy among the staff nurses at selected hospitals."

Member Secretary
Institutional Ethics Committee
DUPMCH, Jalgaon

Copy W/C to:-

1. Mr. Akshay Wankhede Dept. Mental Health Nursing
2. Principal, Godavari College of Nursing for kind information
3. The Chairman Institutional Ethics Committee, DUPMCH Jalgaon
4. The Registrar DUPMCH Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 3058557 Fax : 3058548 E-Mail Id : dupmcj@yahoo.in

Date:- 26/09/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 29/09/20021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 29/09/2021
Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Rahul Prakash Bhavasar.	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the new members of IEC

Minutes of meeting:-

1. According to the criteria of SOP'S of IEC, during re-registration of IEC some members should be changed.
2. So by taking this into consideration member secretory is been changed from Dr. Amrut Mahajan to Dr. Vaishali Nagose and member Dr. Milind Joshi to Dr. Shivaji Sadulwad.
3. Appointment letter will be given to newly appointed members and secrecy and one page CV will be filled from them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr. Rahul Prakash Bhavasar.

Member Secretary

DUPMCH

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date – 29.09.2021

To,

The Concern authority,
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health &Family Welfare, Government of India

Subject: Constitution of Institutional Ethics Committee is under my guidance

Respected sir,

I, **Dr. Narayan Arvikar, Dean of Dr.Ulhas Patil Medical College & Hospital, Jalgaon** has constituted this Institutional Ethics Committee is under my guidance

Sr. No.	Member Name	Designation
1.	Dr. Parag Patil	Chairman
2.	Dr. Rahul P. Bhavasar	Member Secretary
3.	Dr. Shubhangi D. Chaudhari	Member
4.	Dr. Vaishali Nagose	Member
5.	Dr. Shivaji Sadulwad	Member
6.	Dr. Nilesh Bendale	Member
7.	Prof Girish A. kulkarni	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10	Mrs.Swara J.Waghodkar	Member

Thanking you.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr. N. S. Arvikar sir

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 18/08/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 20/08/20021 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 20/08/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the new members of IEC

Minutes of meeting:-

1. According to the criteria of SOP'S of IEC, during re-registration of IEC some members should be changed.
2. So by taking this into consideration member secretory is been changed from Dr. Devendra Chaudhari to Dr. Rahul Prakash Bhavasar and member Dr. Maya Arvikar to Dr. Shubangi Devendra Chaudhari.
3. Appointment letter will be given to newly appointed members and secrecy and one page CV will be filled from them.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date – 20.08.2021

To,

The Concern authority,
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health &Family Welfare, Government of India

Subject: Constitution of Institutional Ethics Committee is under my guidance

Respected sir,

I, **Dr. Narayan Arvikar, Dean of Dr.Ulhas Patil Medical College & Hospital, Jalgaon** has constituted this Institutional Ethics Committee is under my guidance

Sr. No.	Member Name	Designation
1.	Dr. Parag Patil	Chairman
2.	Dr. Rahul P. Bhavasar	Member Secretary
3.	Dr. Shubhangi D. Chaudhari	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Nilesh Bendale	Member
7.	Prof Girish A. kulkarni	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10	Mrs.Swara J.Waghodkar	Member

Thanking you.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr. N. S. Arvikar sir

File No. ECR/1417/Ulhas/Inst/MH/2016

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 30/09/2016

To

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

SUB: - Ethics Committee Registration No. **ECR/852/Inst/MH/2016** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE,** situated at **DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, 1st FLOOR, COLLEGE BUILDING, DUPMCH, JALGAON-425309, MAHARASHTRA, INDIA** with Registration number **ECR/852/Inst/MH/2016** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
2. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

Dr Jlhas Patil Medical College
and Hospital, Jalgaon Kh.
Inward No.: 248

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    I. Basic medical scientist (preferably one pharmacologist)
    II. Clinician
    III. Legal expert
    IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    V. Lay person from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority
Drugs Controller General (I)
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

File No. ECR/1417/Ulhas/Inst/MH/2016

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 30/09/2016

To,

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

Subject: Ethics Committee Registration No. **ECR/852/Inst/MH/2016** issued under Rule 122DD of the Drugs & Cosmetics Rules1945

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. **ECR/852/Inst/MH/2016** with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Ravindrakumar L. Bakal	M.Pharm, PhD	Chairman
2.	Dr. Devendra R. Chaudhari	MD (Pharmacology)	Member Secretary
3.	Dr. Maya N. Arvikar	MD (Obst & Gyane)	Clinician
4.	Dr. Milind P. Joshi	MCH, Pediatric Surgery	Clinician
5.	Dr. Rahul P. Bhavasar	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Sandeep V. Pakhale	MS (Anatomy)	Basic Medical Scientist
7.	Dr. Smita C. Pathade	MD (Pathology)	Basic Medical Scientist
8.	Adv. Satish G. Gadge	LLM	Legal Expert
9.	Mr. Prabhakar M. Jangale	MA, B.Ed	Lay Person
10.	Dr. Prashant S. Warke	BE, MBA (Marketing), PhD (Business Adm.)	Social Scientist
11.	Mr. Sandesh Yashwant Patil	12th Pass	Non Scientific Member

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority
Dte. General of Health Services
Ministry of Health & FW
FDA Bhawan

File No. ECR/1417/Ulhas/Inst/MH/2016

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 30/09/2016

To,

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

Subject: Ethics Committee Registration No. **ECR/852/Inst/MH/2016** issued under Rule 122DD of the Drugs & Cosmetics Rules1945

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. **ECR/852/Inst/MH/2016** with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Ravindrakumar L. Bakal	M.Pharm, PhD	Chairman
2.	Dr. Devendra R. Chaudhari	MD (Pharmacology)	Member Secretary
3.	Dr. Maya N. Arvikar	MD (Obst & Gyane)	Clinician
4.	Dr. Milind P. Joshi	MCH, Pediatric Surgery	Clinician
5.	Dr. Rahul P. Bhavasar	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Sandeep V. Pakhale	MS (Anatomy)	Basic Medical Scientist
7.	Dr. Smita C. Pathade	MD (Pathology)	Basic Medical Scientist
8.	Adv. Satish G. Gadge	LLM	Legal Expert
9.	Mr. Prabhakar M. Jangale	MA, B.Ed	Lay Person
10.	Dr. Prashant S. Warke	BE, MBA (Marketing), PhD (Business Adm.)	Social Scientist
11.	Mr. Sandesh Yashwant Patil	12th Pass	Non Scientific Member

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority

G. N. SINGH
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 20/07/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 21/07/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 21/07/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the CASE REPORT of 3RD YR STUDENT
"GULLIAN BARRE SYNDROME IN A 3 YEAR OLD CHILD".

Minutes of meeting:-

1. **CASE REPORT** was discussed under – title of the **CASE REPORT**, CASE DETAILS REPORTED, any sponsorship by the committee members.
2. It was ensured that CASE REPORT was undertaken as per ICE guidelines.
3. The permission was granted to PUBLIUSH the CASE REPORT by the committee members.
4. Application form for permission of CASE REPORT was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation**

   Guillain Barre Syndrome in a 3 4 can old child : A Rarity

2. **Name of the Principal Investigator/ Under/Post graduate student:**

   Prakruti Paidisetty

3. **Name of the co-investigator/ UG/PG guide/Trial monitor (If applicable)**

   Neeti Navya Sri Motamarry

4. **I) Signature of Principal Investigator/ UG/PG student:** Prakruti

   II) Signature of co-investigator/ UG/PG guide/Trial monitor:

   III) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

   Professor & HOD
   Dept.of Peadiatrics
   Dr.Ulhas Patil Medical College & Hospital Jalgaon Kh,Jalgaon.

   DR. ULHAS PATIL MEDICAL COLLEGE HOSPITAL JALGAON

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submission of application) _____
2) Date of resubmission to IEC _____
3) Date of IEC meeting _____
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: _____

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

1 month

7) Risk factor for the patient (give details):

A) ProceduralL: None.

_____

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Prakash

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

B) Adverse drug reaction (ADRs):

NA

C) Invasive investigations (if any):

NA

D) Explain the measures to counter the above risk factors:

-

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) Details of financial burden involved and how it will be met:

10) Whether the research project is sponsored: YES/NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Prakrut Paidisetty ....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Guillain Barre Syndrome In A 3 Year Old Child: A Rarity.

Kindly do the needful.

Prakrut Paidisetty
Prakrut
(Candidate name and signature)

Dr. Anant G. Bendale.

Dr. Anant G. Bendale

(Guide name and signature)

Professor & HOD
Dept. of Peadiatrics
Hospital Jalgaon Kh. Jalgaon.

(HOD name and Signature with Dept. seal)

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL ★ JALGAON

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 20/05/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 21/05/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 21/05/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To discuss the research study of 3RD YR STUDENT

"Mucourmycosis in covid and non-covid patients, a Tertiary Care Centre study"

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from June 2021 to November 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project/ Dissertation**
   Mucormycosis in post-Covid and Covid patients, a tertiary care centre study.

2. **Name of the Principal Investigator/ Under/~~Post~~ graduate student:**
   Prakruti Vaishnetty

3. **Name of the co-investigator/ UG/~~PG~~ guide/Trial monitor (if applicable)**
   Dr. Vaishali Nagose Rathod.

4. **i) Signature of Principal investigator/ UG/~~PG~~ student:**

   ii) Signature of co-investigator/ UG/~~PG~~ guide/~~Trial~~ monitor:

   iii) Signature of HOD of Principal Investigator/UG/PG student: (with seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

_____

_____

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) **Place where research work will be carried out**

(A) At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and it's analysis:**

6 Months

7) **Risk factor for the patient** (give details):

A) ProceduralL: N.A

B) Adverse drug reaction (ADRs):

N.A

C) Invasive investigations (if any):

N.A

D) Explain the measures to counter the above risk factors:

N.A

8) **Details about research project** : Submitted in Synopsis

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

9) **Details of financial burden involved and how it will be met:** Cost of investigation of serum iron, HbA1C

10) **Whether the research project is sponsored:** YES/NO

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).
(DUPMC)

11) **Any other relevant information:**

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Prakruti

Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, ~~Dr.~~ Prakruti Laidiretty hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Mucormycosis in post-COVID patients: A tertiary care center study.

Kindly do the needful.

Prakruti Laidiretty

Prakruti

(Candidate name and signature)

(Guide name and signature)

(HOD name and signature with Dept. seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 08/05/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 10/05/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 10/05/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Covering letter

Through Proper Channel Only

Date - 25/08/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs.....SHWETA A. MANDLIK.....hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON, MAHARASHTRA, INDIA.

Kindly do the needful.

SHWETA A. MANDLIK
(Principal Investigator name and signature)

(Guide name and signature)

(HOD name and Signature with Dept. seal)

Professor & Head
Dept. of Gen. Surgery
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh., Jalgaon

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	**Title of the Research Project/ Dissertation** PREVALENCE OF RISK FACTORS IN KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA	
		Signature
2.	**Name of the Principal Investigator/ Under/Post graduate student:** SHWETA A. MANDLIK	
3.	**Name of the co-investigator/s (if applicable)** i) DR. SHRIYASH SONAWANE ii) iii) iv)	
4.	**Name of UG/PG guide**	
5.	**Name of Trial monitor / co-guide** DR. SHIVAJI P. SADULWAD	H.O.D. Department of Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh. Jalgaon
6.	**HOD of Principal Investigator/UG/PG student:** DR. SHIVAJI P. SADULWAD	(With seal) Professor & Head Dept. of Gen. Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh., Jalgaon
7.	**HOD of other Departments involved**	(With seal)

8.	**Place where research work will be carried out**	
	a. At DUPMC&	Yes / No
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	**Time period required for completion of research project and it's analysis** (Approximately)	From –To (Date) 29/04/21 – 30/05/22
10.	**Risk factor for the patient** (give details): A) Procedural	
	B) Adverse drug reaction (ADRs)	
	C) Invasive investigations (if any)	
	D) Explain the measures to counter the above risk factors.	

11.	**Details about research project must include**	Yes	No
	(a) Project title	yes	
	(b) Aims and objectives:	yes	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	yes	
	(d) Materials and methods (Research plan and its implications)	yes	
	(e) Statistical analysis	yes	
	(f) Conflict of interest:	yes	
	(g) Risk factors:	yes	
	(h) List of references:	yes	

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

12.	**Details of financial burden involved and how it will be met:**	
13.	**Whether the research project is sponsored:**	Yes / No
14.	**Sponsoring authority:** (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	**Any other relevant information:**	

16. **Enclosures:**

		Attached	Not attached	Not applicable
1	Patient information sheet	✓		
2	Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi)	✓		
3	Case Record Form (CRF)	✓		
4	Undertaking by the investigator	✓		
5	Stability testing of new drug			✓
6	Content of the proposed protocol for conducting clinical trial			✓
7	Data elements for reporting Serious ADR/ADE occurring in clinical trial.			✓
8	Study Flow Chart if any.	✓		
9	Newspaper publication matter for subject recruitment if any.			✓
10	Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature
Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

(For IEC Office use only)

1	Sr. No given to project	~~25.04.2024~~
2	Department	G. Surgery
3	Date of Receipt by IEC (submission of application)	25.04.2024
4	Date of resubmission to IEC	10.05.2024
5	Date of IEC meeting	10.05.2024
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved.
7	IEC decision conveyed on date	10.05.2024

CHAIRPERSON
IEC, DUPMCH

IEC DUPMCH JALGAON

MEMBER SECRETARY
IEC, DUPMCH

1. Title: Prevalence of risk factors in kidney stone patients in tertiary care centre in Jalgaon, Maharashtra, India

2.Introduction

- Kidney stone disease is a common clinical problem worldwide. It is the formation of stones in kidney by the successive physicochemical events of supersaturation, nucleation and aggregation, which eventually culminates in retention of stone.
- The epidemiology of nephrolithiasis differs according to geographical area in terms of prevalence and incidence, age and sex distribution, eating habits, sources of drinking water etc. Data studies show rising global prevalence of nephrolithiasis. Risk of developing nephrolithiasis in adults appears to be higher in the West (4% in Germany, 5-9% in Europe, 10-12% in Canada and 13-15% in US) than in the East. Nephrolithiasis is common in ages of 40-49 years in the US; 50-59yrs in Japan. High risk of nephrolithiasis has also been found in Asian and third world countries such as Saudi Arabia, India, Malaysia, Thailand etc.
- In India, urolithiasis affects 2 million people every year. The "stone belt" occupies parts of Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and states of North east. Stone patients from North India were found to have a high rate of consumption of oxalate rich foods, dairy products, and alcohol. In India, 12% of population is estimated to have renal stones, out of which 50% may progress to renal damage or loss of renal function. Nearly 15% of people from Northern India are affected with kidney stones. Prevalence of nephrolithiasis in Indian males is 10.60% while that is females is 7.10%.
- Kidney stone disease has gained increasing significance because of its rising prevalence, and also due to its tendency to recur within 5 to 10 years. Epidemiological studies indicate that factors like age, sex, race, ethnicity, geography, climate, occupation, socioeconomic status, daily water intake and dietary habits of an individual influence kidney stone formation and recurrence.

- Food patterns are among the major factors for renal stone formation. In the context of Indian diet, there is a collection of different tastes and food products. Several communities in the country are vegetarian, although there is still a large range of non-vegetarian recipes. Increased urinary

calcium excretion is attributed to animal proteins. Oxalate stones are a result of diets rich in spinach, tomatoes, beetroot, sweet potatoes and almonds. This food pattern in Indian culture attributes to high incidence of nephrolithiasis specially in the "stone belt". An equally crucial factor is the frequency or amount of water consumption, hard/soft water and the sources from which these populations obtain drinking water.

3. OBJECTIVE

- Primary objective:
- The aim of the study is to determine the prevalence of risk factors in kidney stone patients in our hospital-a tertiary care centre in Jalgaon.
- Secondary objective:
- To provide evidence for the formulation of evidence-based changes in lifestyle and eating habits, as well as creating awareness regarding preventive measures.
- To update an essential database with details of patients with kidney stones, highlighting the risk factors which attribute to the condition.

4. METHODOLOGY:

- The type of study is Cross-sectional type of epidemiological study.
- Study setting- The data will be collected from patients who are currently admitted to the Surgery ward of our hospital with diagnosis of renal calculi.
- Study period- Total of 9 months from May 2021 to February 2022.
- Study population- All voluntary symptomatic patients diagnosed with kidney stones and admitted to our hospital.
- All patients in the sample of 100 are given self-administered questionnaire and relevant information is obtained by medical case history.

5. METHOD OF COLLECTION OF DATA

- This is a hospital-based study conducted in Department of Surgery, DUPMC&H, Jalgaon, Maharashtra, India.

- After taking written informed consent, patients with clinical features of nephrolithiasis and radiological confirmation of obstructive calculus will be included.
- Information regarding residential address, daily volume of water consumption, eating habits, and source of drinking water will be collected from 100 patients with obstructive kidney stones.
- Some of the relevant information about the patients will be obtained from medical case history.

- Inclusion Criteria:
  - Age between 10 and 80 years
  - Temperature- afebrile or below 37 C/98.4 F
  - Pulse between 60 to 100 beats per minute
  - History of vaccination

- Exclusion Criteria:
  - Age less than 10 and more than 80 years
  - Previously operated for renal stones
  - Temperature- above 37.5 C/ 99.5 F

6. Data collected which will be coded, entered, validated and analysed using Microsoft Excel.

7. ETHICAL APPROVAL

The current study will be carried after approval by ethical committee of hospital. The study involves analyses of available data. The study maintains confidentiality of all the patients involved.

8. IMPLICATIONS

- Data obtained from this study can be utilized for screening larger population for better public health.
- To review the trends of nephrolithiasis in our hospital as this study has not been conducted previously.
- To create awareness among the local population regarding risk factors and possible preventive measures.

9. REFERENCES

1. Prakash R, Arunachalam, Narayanasamy. Prevalence and socio-demographic status on kidney stone patients in Thanjavur district, Tamil Nadu, India. Int J Community Med Public Health 2019;6:1943-7..
2. Faridi MS, Singh KS. Preliminary study of prevalence of urolithiasis in North-Eastern city of India. *J Family Med Prim Care*. 2020;9(12):5939-5943. Published 2020 Dec 31. doi:10.4103/jfmpc.jfmpc_1522_20.
3. Mitra, Pubali & Pal, Dilip & Das, Madhusudan. (2018). Does quality of drinking water matter in kidney stone disease: A study in West Bengal, India. Investigative and Clinical Urology. 59. 158. 10.4111/icu.2018.59.3.158..
4. Sofia, H.Nalini & Manickavasakam.K, & Walter, Thomas M.. (2016). PREVALENCE AND RISK FACTORS OF KIDNEY STONE. Global journal for Research Analysis. volume 5. page 183-187.
5. Khalili P, Jamali Z, Sadeghi T, Esmaeili-Nadimi A, Mohamadi M, Moghadam-Ahmadi A, Ayoobi F, Nazari A. Risk factors of kidney stone disease: a cross-sectional study in the southeast of Iran. BMC Urol. 2021 Oct 8;21(1):141. doi: 10.1186/s12894-021-00905-5. PMID: 34625088; PMCID: PMC8499392.
6. Shah P, Baral R, Agrawal CS, Lamsal M, Baral D, Khanal B. Urinary Calculi: A Microbiological and Biochemical Analysis at a Tertiary Care Hospital in Eastern Nepal. Int J Microbiol. 2020 Sep 12;2020:8880403. doi: 10.1155/2020/8880403. PMID: 33005194; PMCID: PMC7503111.

NAME	AGE	SEX	OCCUPATION	RESIDENCE	TYPE OF FAMILY	FAMILY HISTORY	SMOKING	ALCOHOL	SOURCE OF DRINKING WATER	FREQ. OF URINATION	ANY COMORBIDITY	FREQ. OF INTAKE OF OXALATE RICH FOOD	FREQ.OF INTAKE OF MEAT	SR.CREATININE(mg/dl)	SR.UREA(IU/L)	DAILY WATER INTAKE	CT SCAN FINDING(cm)largest stone size	LOCATION OF OBSTRUCTIVE CALCULI		TOTAL NO. OF STONES

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

   SHWETA A. MANDLIK
   T-1, 904, CAPITOL HEIGHTS
   MEDICAL SQUARE, NAGPUR - 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

   DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
   NH-6, BHUSAWAL ROAD
   JALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

   NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

   IEC, DUPMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

   NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

   PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON, MAHARASHTRA, INDIA

7. Commitments:
   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

25/04/27

8. Signature of Investigator with date.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Covering letter

Through Proper Channel Only

Date - 25/08/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. SHWETA A. MANDLIK ..... hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON MAHARASHTRA, INDIA.

Kindly do the needful.

SHWETA A. MANDLIK

(Principal Investigator name and signature)

(Guide name and signature)

Professor & Head
Dept. of Gen. Surgery
Dr.Ulhas Patil Medical College
& Hospital,Jalgaon Kh.,Jalgaon

(HOD name and Signature with Dept. seal)

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	Title of the Research Project/ Dissertation PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA.	
		Signature
2.	Name of the Principal Investigator/ Under/Post graduate student: SHWETA A. MANDLIK	
3.	Name of the co-investigator/s (if applicable) i) DR. SHRIYASH SONAWANE ii) iii) iv)	
4.	Name of UG/PG guide DR. SHIVAJI P. SADULWAD.	
5.	Name of Trial monitor / co-guide	
6.	HOD of Principal Investigator/UG/PG student: DR. SHIVAJI SADULWAD	(With seal) HOD. Department of Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh. Jalgaon Professor & Head Dept. of Gen. Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh., Jalgaon
7.	HOD of other Departments involved	(With seal)

8.	**Place where research work will be carried out**	✓
	a. At DUPMC&	Yes / No
	b. Outside DUPMC&H.	Yes / No ✓
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	**Time period required for completion of research project and it's analysis** (Approximately)	From –To (Date) 29.04.21 – 30.05.21
10.	**Risk factor for the patient** (give details): A) Procedural	
	B) Adverse drug reaction (ADRs)	
	C) Invasive investigations (if any)	
	D) Explain the measures to counter the above risk factors.	

11.	**Details about research project must include**	Yes	No
	(a) Project title		
	(b) Aims and objectives:		
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic		
	(d) Materials and methods (Research plan and its implications)		
	(e) Statistical analysis		
	(f) Conflict of interest:		
	(g) Risk factors:		
	(h) List of references:		

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

12.	**Details of financial burden involved and how it will be met:**	
13.	**Whether the research project is sponsored:**	Yes / No
14.	**Sponsoring authority:** (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	**Any other relevant information:**	

16. **Enclosures:**

		Attached	Not attached	Not applicable
1	Patient information sheet	✓		
2	Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi)	✓		
3	Case Record Form (CRF)	✓		
4	Undertaking by the investigator	✓		
5	Stability testing of new drug			✓
6	Content of the proposed protocol for conducting clinical trial			✓
7	Data elements for reporting Serious ADR/ADE occurring in clinical trial.			✓
8	Study Flow Chart if any.	✓		
9	Newspaper publication matter for subject recruitment if any.			✓
10	Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature

Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

INSTITUTIONAL ETHICS COMMITTEE
DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

(For IEC Office use only)

1	Sr. No given to project	
2	Department	General Surgery
3	Date of Receipt by IEC (submission of application)	25.04.2024
4	Date of resubmission to IEC	10.05.24
5	Date of IEC meeting	10.05.24
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	10.05.24

CHAIRPERSON
IEC, DUPMCH

IEC, DUPMCH JALGAON

MEMBER SECRETARY
IEC, DUPMCH

1. Title: Prevalence of risk factors in kidney stone patients in tertiary care centre in Jalgaon, Maharashtra, India

2.Introduction

- Kidney stone disease is a common clinical problem worldwide. It is the formation of stones in kidney by the successive physicochemical events of supersaturation, nucleation and aggregation, which eventually culminates in retention of stone.
- The epidemiology of nephrolithiasis differs according to geographical area in terms of prevalence and incidence, age and sex distribution, eating habits, sources of drinking water etc. Data studies show rising global prevalence of nephrolithiasis. Risk of developing nephrolithiasis in adults appears to be higher in the West (4% in Germany, 5-9% in Europe, 10-12% in Canada and 13-15% in US) than in the East. Nephrolithiasis is common in ages of 40-49 years in the US; 50-59yrs in Japan. High risk of nephrolithiasis has also been found in Asian and third world countries such as Saudi Arabia, India, Malaysia, Thailand etc.
- In India, urolithiasis affects 2 million people every year. The "stone belt" occupies parts of Maharashtra, Gujarat, Rajasthan, Punjab, Haryana, Delhi and states of North east. Stone patients from North India were found to have a high rate of consumption of oxalate rich foods, dairy products, and alcohol. In India, 12% of population is estimated to have renal stones, out of which 50% may progress to renal damage or loss of renal function. Nearly 15% of people from Northern India are affected with kidney stones. Prevalence of nephrolithiasis in Indian males is 10.60% while that is females is 7.10%.
- Kidney stone disease has gained increasing significance because of its rising prevalence, and also due to its tendency to recur within 5 to 10 years. Epidemiological studies indicate that factors like age, sex, race, ethnicity, geography, climate, occupation, socioeconomic status, daily water intake and dietary habits of an individual influence kidney stone formation and recurrence.

- Food patterns are among the major factors for renal stone formation. In the context of Indian diet, there is a collection of different tastes and food products. Several communities in the country are vegetarian, although there is still a large range of non-vegetarian recipes. Increased urinary

calcium excretion is attributed to animal proteins. Oxalate stones are a result of diets rich in spinach, tomatoes, beetroot, sweet potatoes and almonds. This food pattern in Indian culture attributes to high incidence of nephrolithiasis specially in the "stone belt". An equally crucial factor is the frequency or amount of water consumption, hard/soft water and the sources from which these populations obtain drinking water.

3. OBJECTIVE

- Primary objective:
- The aim of the study is to determine the prevalence of risk factors in kidney stone patients in our hospital-a tertiary care centre in Jalgaon.
- Secondary objective:
- To provide evidence for the formulation of evidence-based changes in lifestyle and eating habits, as well as creating awareness regarding preventive measures.
- To update an essential database with details of patients with kidney stones, highlighting the risk factors which attribute to the condition.

4. METHODOLOGY:

- The type of study is Cross-sectional type of epidemiological study.
- Study setting- The data will be collected from patients who are currently admitted to the Surgery ward of our hospital with diagnosis of renal calculi.
- Study period- Total of 9 months from May 2021 to February 2022.
- Study population- All voluntary symptomatic patients diagnosed with kidney stones and admitted to our hospital.
- All patients in the sample of 100 are given self-administered questionnaire and relevant information is obtained by medical case history.

5. METHOD OF COLLECTION OF DATA

- This is a hospital-based study conducted in Department of Surgery, DUPMC&H, Jalgaon, Maharashtra, India.

- After taking written informed consent, patients with clinical features of nephrolithiasis and radiological confirmation of obstructive calculus will be included.
- Information regarding residential address, daily volume of water consumption, eating habits, and source of drinking water will be collected from 100 patients with obstructive kidney stones.
- Some of the relevant information about the patients will be obtained from medical case history.

- Inclusion Criteria:
  - Age between 10 and 80 years
  - Temperature- afebrile or below 37 C/98.4 F
  - Pulse between 60 to 100 beats per minute
  - History of vaccination

- Exclusion Criteria:
  - Age less than 10 and more than 80 years
  - Previously operated for renal stones
  - Temperature- above 37.5 C/ 99.5 F

6. Data collected which will be coded, entered, validated and analysed using Microsoft Excel.

7. ETHICAL APPROVAL

The current study will be carried after approval by ethical committee of hospital. The study involves analyses of available data. The study maintains confidentiality of all the patients involved.

8. IMPLICATIONS

- Data obtained from this study can be utilized for screening larger population for better public health.
- To review the trends of nephrolithiasis in our hospital as this study has not been conducted previously.
- To create awareness among the local population regarding risk factors and possible preventive measures.

9. REFERENCES

1. Prakash R, Arunachalam, Narayanasamy. Prevalence and socio-demographic status on kidney stone patients in Thanjavur district, Tamil Nadu, India. Int J Community Med Public Health 2019;6:1943-7..
2. Faridi MS, Singh KS. Preliminary study of prevalence of urolithiasis in North-Eastern city of India. *J Family Med Prim Care*. 2020;9(12):5939-5943. Published 2020 Dec 31. doi:10.4103/jfmpc.jfmpc_1522_20.
3. Mitra, Pubali & Pal, Dilip & Das, Madhusudan. (2018). Does quality of drinking water matter in kidney stone disease: A study in West Bengal, India. Investigative and Clinical Urology. 59. 158. 10.4111/icu.2018.59.3.158..
4. Sofia, H.Nalini & Manickavasakam.K, & Walter, Thomas M.. (2016). PREVALENCE AND RISK FACTORS OF KIDNEY STONE. Global journal for Research Analysis. volume 5. page 183-187.
5. Khalili P, Jamali Z, Sadeghi T, Esmaeili-Nadimi A, Mohamadi M, Moghadam-Ahmadi A, Ayoobi F, Nazari A. Risk factors of kidney stone disease: a cross-sectional study in the southeast of Iran. BMC Urol. 2021 Oct 8;21(1):141. doi: 10.1186/s12894-021-00905-5. PMID: 34625088; PMCID: PMC8499392.
6. Shah P, Baral R, Agrawal CS, Lamsal M, Baral D, Khanal B. Urinary Calculi: A Microbiological and Biochemical Analysis at a Tertiary Care Hospital in Eastern Nepal. Int J Microbiol. 2020 Sep 12;2020:8880403. doi: 10.1155/2020/8880403. PMID: 33005194; PMCID: PMC7503111.

NAME	AGE	SEX	OCCUPATION	RESIDENCE	TYPE OF FAMILY	FAMILY HISTORY	SMOKING	ALCOHOL	SOURCE OF DRINKING WATER	FREQ. OF URINATION	ANY COMORBIDITY	FREQ. OF INTAKE OF OXALATE RICH FOOD	FREQ.OF INTAKE OF MEAT	SR.CREATININE(mg/dl)	SR.UREA(IU/L)	DAILY WATER INTAKE	CT SCAN FINDING(cm)largest stone size	LOCATION OF OBSTRUCTIVE CALCULI		TOTAL NO. OF STONES

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

   SHWETA A. MANDLIK
   T-1, 904, CAPITOL HEIGHTS
   MEDICAL SQUARE, NAGPUR - 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

   DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
   NH-6, BHUSAWAL ROAD
   JALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

   NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

   IEC, DUPMC&H, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

   NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

   PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON, MAHARASHTRA, INDIA.

7. Commitments:
   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.



25/04/21

3. Signature of Investigator with date.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

Covering letter

Through Proper Channel Only

Date - 25/04/21

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr/Mr/ Mrs. SHWETA A. MANDLIK hereby submitting synopsis of my research protocol/ PG dissertation for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON, MAHARASHTRA, INDIA.

Kindly do the needful.

SHWETA A. MANDLIK
(Principal Investigator name and signature)

(Guide name and signature)

Professor & Head
Dept. of Gen. Surgery
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh., Jalgaon

(HOD name and Signature with Dept. seal)

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.
(*To be preserved by IEC for minimum 15 years.)

1.	Title of the Research Project/ Dissertation PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CENTRE IN JALGAON, MAHARASHTRA, INDIA.	
		Signature
2.	Name of the Principal Investigator/ Under/Post graduate student: SHWETA A. MANDLIK	
3.	Name of the co-investigator/s (if applicable) i) DR. SHRIYASH SONAWANE ii) iii) iv)	
4.	Name of UG/PG guide	
5.	Name of Trial monitor / co-guide DR. SHIVAJI SADULWAD	
6.	HOD of Principal Investigator/UG/PG student: DR. SHIVAJI SADULWAD	(With seal) Professor & Head Dept. of Gen. Surgery Dr. Ulhas Patil Medical College & Hospital, Jalgaon Kh., Jalgaon
7.	HOD of other Departments involved	(With seal)

8.	**Place where research work will be carried out**	
	a. At DUPMC&	Yes / No
	b. Outside DUPMC&H.	Yes / No
	(Permission letter to be submitted if outside DUPMC&H)	Yes / No
9.	**Time period required for completion of research project and it's analysis** (Approximately)	From –To (Date) 29/04/2021 – 30/05/2022
10.	**Risk factor for the patient** (give details): A) Procedural	
	B) Adverse drug reaction (ADRs)	
	C) Invasive investigations (if any)	
	D) Explain the measures to counter the above risk factors.	

11.	**Details about research project must include**	Yes	No
	(a) Project title	yes	
	(b) Aims and objectives:	yes	
	(c) Introduction (Current knowledge about the research subject) shortly why you have chosen this topic	yes	
	(d) Materials and methods (Research plan and its implications)	yes	
	(e) Statistical analysis	yes	
	(f) Conflict of interest:	yes	
	(g) Risk factors:	yes	
	(h) List of references:	yes	

12.	**Details of financial burden involved and how it will be met:**	
13.	**Whether the research project is sponsored:**	Yes / No ✓
14.	**Sponsoring authority:** (mention the name) (1) Industry (2) Government (3) University (4) ICMR (5) Any other (give details).	
15.	**Any other relevant information:**	

16. **Enclosures:**

		Attached	Not attached	Not applicable
1	Patient information sheet	✓		
2	Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi)	✓		
3	Case Record Form (CRF)	✓		
4	Undertaking by the investigator	✓		
5	Stability testing of new drug			✓
6	Content of the proposed protocol for conducting clinical trial			✓
7	Data elements for reporting Serious ADR/ADE occurring in clinical trial.			✓
8	Study Flow Chart if any.	✓		✗
9	Newspaper publication matter for subject recruitment if any.			✓
10	Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.			✓

(Attach 10 hard copies of enclosures + 10 hard copies of RESEARCH PROTOCOL and after IEC APPROVAL submit one soft copy to IEC, DUPMCH, JALGAON.)

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature
Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

(For IEC Office use only)

1	Sr. No given to project	
2	Department	G.. Surgery
3	Date of Receipt by IEC (submission of application)	25.04.24
4	Date of resubmission to IEC	10.05.24
5	Date of IEC meeting	10.05.24
6	Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED	Approved
7	IEC decision conveyed on date	10.05.24

CHAIRPERSON
IEC, DUPMCH

IEC, DUPMCH, JALGAON

MEMBER SECRETARY
IEC, DUPMCH

Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)

   SHWETA A. MANDLIK
   T-1, 904, CAPITOL HEIGHTS
   MEDICAL SQUARE, NAGPUR- 440003

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

   DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL
   NH-6, BHUSAWAL ROAD
   JALGAON - 425309

3. Name and address of all clinical laboratory facilities to be used in the study.

   NIL

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

   IEC, DUPMCH, Jalgaon

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.

   NIL

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

   PREVALENCE OF RISK FACTORS FOR KIDNEY STONE PATIENTS IN TERTIARY CARE CENTRE IN JALGAON, MAHARASHTRA, INDIA

7. Commitments:
   i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
   ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate

hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

iii. I agree to personally conduct or supervise the clinical trial at my site.

iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data. xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

25/04/21

8. Signature of Investigator with date.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 17/02/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 18/02/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 18/02/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of **Dr. Vaishali Nagose (Prof. Department of Pathology, DUPMCH)**

"Effect of recent IAC guidelines for serous fluid cytology reporting, repeat sampling and cell block on atypical cell categories in serous fluid cytology".

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from March 2021 to April 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. Title of the Research Project/ Dissertation
Effect of Recent IAC Guidelines for Serous Fluid Cytology Reporting, Repeat Sampling and de Cell block on Atypical Cells Catagories in Serous Fluid Cytology.

2. Name of the Principal Investigator/ ~~Under/Post graduate student:~~
Dr. Vaishali Nagose

3. Name of the co-investigator/ ~~UG/PG guide/Trial monitor~~ (if applicable)
Dr. Shirish Gondane

4. i) Signature of Principal investigator/ ~~UG/PG student:~~
Nagose.

ii) Signature of co-investigator/ ~~UG/PG guide/Trial monitor:~~

iii) Signature of HOD of Principal Investigator/~~UG/PG student:~~ (with seal)

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

iv) Signature of HOD of other Departments involved (with seal):

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submissi-----on of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out

✓
(A)At DUPMC&H (B) Outside DUPMC&H.

(Permission letter to be submitted if outside DUPMC&H)

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

2 months

7) Risk factor for the patient (give details):

A) ProceduralL: None

B) Adverse drug reaction (ADRs):

_____

C) Invasive investigations (if any):

_____

D) Explain the measures to counter the above risk factors:

_____

8) Details about research project

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

As mentioned in synopsis.

9) Details of financial burden involved and how it will be met: —

10) Whether the research project is sponsored: ~~YES~~/NO ✓

Sponsoring authority: (1) Industry (2) Government (3) University (4) ICMR
(5) Any other (give details).

11) Any other relevant information:

_____
—

_____
—

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).
(c) Case Record Form (CRF)
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.



Signature of Principal Investigator.

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

Respected Sir/Madam,

I the undersigned, Dr. Dr. Vaishali Nagose .....hereby submitting synopsis of my research protocol/ ~~PG dissertation~~ for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis
Effect of Recent IAC Guidelines for Serous Fluid Cytology Reporting, Repeat Samplings & Cell Block on Atypical Cells Categories in Serous Fluid Cytology.

Kindly do the needful.

Nagose.
Dr. Vaishali Nagose
(Candidate name and signature)

Co Investigator
(~~Guide~~ name and signature)
Dr. Shirish Gondane.

(HOD name and signature with Dept. seal)
Dr Anagha Amde Chopade
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

Effect of Recent IAC Guidelines for Serous Fluid Cytology Reporting, Repeat Sampling and Cell Block on Atypical Cells Categories in Serous Fluid Cytology.

Cytological examination of body fluids has increasingly gained acceptance in clinical medicine to such extent that once positive diagnosis is made often considered definitive diagnosis and it is paramount important to identify primary site and type of malignancy. This can help to obviate the proper surgical management, chemotherapy and radiotherapy so as to increase patients' survival rate[1,2].

Established international reporting terminology systems are already in place for cervical,[3] urinary tract,[4] thyroid,[5] salivary gland,[6] pancreatico-biliary,[7] and pulmonary cytology.[8] As of now, there is absence of a globally accepted and widely used reporting terminology system for serous effusion cytology samples. However, for reporting effusion cytology specimens, there was no consistent and reproducible reporting system until recently. Not long ago, the international system for reporting serous fluid cytopathology was announced.[9] In the beginning of year 2020. Also, Recently the Indian Academy of Cytologists (IAC) has published the guidelines for interpretation and reporting of serous effusions [10]. Till date, there are only occasional studies on its applicability. However, the criteria for diagnosis of the atypical cells if strictly followed, promise to reduce the number of entries in this group.

A major diagnostic challenge lies in the distinction of atypical/reactive mesothelial cells from malignant adenocarcinoma cells. Smears may be reported initially as atypical on cytology, probably misinterpreted due to overlapping cytomorphological features. Both architecturally and cytologically reactive mesothelial cells may pose a diagnostic challenge. Detection of malignant cells on effusion cytology in these patients becomes at times difficult.

Conventional smear is a much simpler procedure than that of cell block technique, it has lower sensitivity in these cases because of overcrowding of cells, cell loss, lack of architecture and also, abundance of inflammatory cells and paucity of representative cells contribute to considerable difficulties in making conclusive diagnosis on conventional smears [11,12]. Cell block technique is one of the oldest method has advantages like it concentrates minimal amount of cellular material in one small area that can be evaluated at a glance with all cells lying in the same focal plane of the microscope, and as it uses of histological techniques it gives better cellular morphology better nuclear and cytoplasmic preservation, intact cell membrane and crisp chromatin details , preservation of architectural pattern like cell balls, papillae, acini, rosettes and individual cell characteristic, representing its primary site of malignancy, fragment of this tissue can easily interpreted in a biopsy-like fashion [11,12]. On the other hand as multiple section of same material can be obtained for special stains and immunohistochemistry. And also the possibility of storing slides for retrospective studies also done , as storage of the conventional smears is a practical problem [1,2] . These advantages of the CB can give the advent of sorting the atypical cells into the malignant or benign group upto a certain extent.

If there is a suspicion of malignancy on clinical/imaging grounds, a repeat cytology evaluation has been proven to be of use. It is also known to have a potential to change the categories such as atypical /suspicious of malignancy to move them into clear cut benign and malignant categories on repeat sampling and/or ancillary testing.[13]

Aims:

1. To assess the feasibility of applying the IAC reporting categories to effusions, determine the frequency of various categories including atypical cases.
2. To compare the categorization after the repeat sampling in these atypical category cases.
3. To compare the categorization after the study of cell block prepared from these cases.

Materials and Methods: The study will be carried out in accordance with the standards laid down in the Helsinki Declaration. Relevant details will be noted from the sample requisition forms. Medical records will be searched for the clinical, radiological, and histopathological follow-up. Cases with no hospital record of malignancy in one year will be presumed to have a benign course. Categorization of cases as per the recent IAC Guidelines for interpretation and reporting of serous effusion samples will be done.[10] Papanicolaou smears of fluid cytology samples received over calendar years January 2018 to June 2021 will be reviewed retrospectively by an expert in cytopathology blinded to the final clinical and/or histopathological diagnoses. Cases with discrepancies after review will be noted. Data were analyzed using SPSS version 16.

References:

1. Koss LG et al: Effusions in the presence of cancer. In Koss' Diagnostic Cytology and its Histopathologic Bases, 5th edition. Edited by Koss LG, Melamed MR, Vol 2, Philadelphia :Lippincott, Williams & wilkins 2006, 950-951.

2. Dekker A, Bupp PA. Cytology of serous effusions. An investigation into the usefulness of cellblocks versus smears. Am J Clin Pathol 1978;70 (6):855-860.

3. Nayar R, Wilbur DC. The Bethesda system for reporting cervical cytology: A historical perspective. Acta Cytol 2017;61:359-72.

4. Barkan GA, Wojcik EM, Nayar R, Savic-Prince S, Quek ML, Kurtycz DF, et al. The Paris system for reporting urinary cytology: The quest to develop a standardized terminology. Acta Cytol 2016;60:185-97.

5. Cibas ES, Ali SZ. The 2017 Bethesda system for reporting thyroid cytopathology. Thyroid 2017;27:1341-6.

6. Rossi ED, Faquin WC, Baloch Z, Barkan GA, Foschini MP, Pusztaszeri M, et al. The Milan system for reporting salivary gland cytopathology: Analysis and suggestions of initial survey. Cancer Cytopathol 2017;125:757-66.

7. Pitman MB, Layfield LJ. Guidelines for pancreaticobiliary cytology from the Papanicolaou society of cytopathology: A review. Cancer Cytopathol 2014;122:399-411.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 07/01/2021

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 08/01/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 08/01/2021

Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three OBGY and two Pediatrics PGs-

1	Dr. DONGARWAR AKASHKUMAR SHALIKRAM	AN OBSERVATIONAL STUDY OF INTRAOPERATIVE DIFFICULTIES IN REPEAT CAESAREAN SECTION COMING TO TERTIARY CARE HOSPITAL
2	Dr. MAHESH GAJANAN DESHMUKH	TRANSABDOMINAL ULTRASOUND ASSESSMENT OF FETAL OCCIPUT - SPINE ANGLE TO PREDICT THE MODE OF DELIVERY
3	Dr. YASHASHREE PRADIP DESHMUKH	A STUDY OF UTERINE ARTERY DOPPLER FOR PREDICTION OF PREECLAMPSIA FROM 12 TO26 WEEKS OF GESTATION IN TERTIARY CARE CENTER.
4	Dr. RANGNEKAR PRADNIL KISHOR	CLINICAL PROFILE OF LOW BIRTH WEIGHT NEONATES ADMITTED IN NICU AT TERTIARY CARE CENTER
5	Dr. SHUKLA SURUCHI RAMPRASAD	PROSPECTIVE STUDY OF CLINICAL OUTCOME OF EARLY DISCHARGED VERY LOW BIRTH WEIGHT BABIES FROM NICU AT WEIGHT BETWEEN 1300GMS TO 1800GMS.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project: Study of Association of E-Selectin and Hematological Parameters In Patients of Sickle Cell Disease.**

2. **Name of the Principal Investigator**
   Dr .Anagha Amale (Chopade), Professor, Pathology Department
   DUPMC, Jalgaon.

3. **Name of the co-investigator**
   Dr. Uditkumar Agrawal, Associate Professor, BiochemistryDepartment, GMC, Khandwa.

4. **i) Signature of Principal Investigator** Apamale.

   ii) Signature of co- investigator/ gms

   iii) Signature of HOD of Principal Investigator (with seal)

Apamale.
Professor & HOD
Dept. of Pathology
Dr Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

(For IEC Office use only) **Sr. No**_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC _____
3) Date of IEC meeting
4) Decision of IEC: APPROVED/ REGUR

5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) Place where research work will be carried out
At DUPMC&H

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) Time period required for completion of research project and it's analysis:

3 months.

7) Risk factor for the patient (give details): None.

5) Details about research project-Synopsis Attached

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

8) Details of financial burden involved and how it will be met: Nofinancial burden.

9) Whether the research project is sponsored: Yes.
Sponsoring authority: Self.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).

(c) **Case Record Form (CRF)**

(d) Undertaking by the investigator (Appendix VII)

(e) Stability testing of new drug (Appendix IX)

(f) Content of the proposed protocol for conducting clinical trial (Appendix X)

(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)

(h) Study Flow Chart if any.

(i) News paper publication matter for subject recruitment if any.

(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

I the undersigned, Dr Anagha Amale (Chopade) hereby submitting synopsis of my research protocol for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis: Study of Association of E-Selectin and Hematological parameters in patients of Sickle Cell Disease.

Kindly do the needful.

Dr Anagha Amale
(Candidate name and signature)

Dr Anagha Amale
(HOD name and Signature with Dept. seal)

(Guide name and signature)

CASE RECORD FORM

1. Full name of the Subject
2. Age
3. Gender
4. Height
5. Weight
6. Blood Pressure
7. Pulse
8. Pallor
9. Icterus
10. Family History
11. History of Present Illness

12. Any other associated Disorders/Diseases:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled "**Study of Association of E-Selectin, Hematological and Biochemical Parameters in patients of Sickle Cell Disease** ". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled **"Prevalence of Sickle Cell Disorders in patients visited to Tertiary Care Hospital"**. I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled "**Hematological indices, electrolyte status & effect of micronutrients and vitamins on polymerization in sickle cell disease at rural based tertiary care hospital**". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Research Protocol

Title of the Research Project: Study of Association of E-Selectin and Hematological Parameters in Patients of Sickle Cell Disease.

Introduction: In patients of sickle cell disease, there was statistically significant variation in the red cell indices. Very few studies have been shown less commonly determined variables such as erythrocyte indices like MCV, MCH, MCHC width in this region of India.(1-6)

Aim: To find the association of E-Selectin and Hematological Parameters In Patients of Sickle Cell Disease.

Objectives: 1.To find relationship between E-selectin and hematological parameters.

2. to find relationship between E-selectin and other biochemical parameters.

Materials and methods:Invasive investigations: The parameters analyzed will be plasma soluble E selectin, hemoglobin, total RBC Count, total leukocyte count(TLC), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration(MCHC) and other parameters like serum SGPT, SGOT, RBS, Creatinine, Urea parameters. Observations will be analyzed statistically by SPSS version 20.

Study type: Prospective study

Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

Conflict of interest: None

Risk factors: None

Bibliography/List of references:

1. Deore A.U.and Zade S.B. Epidemiology of sickle cell disorder: The urban scenario in Maharashtra, India, International Journal of Public Health and Epidemiology, 2013; 2(5) 101-107.
2. Kamble M. and Chatruvedi P.Epidemiology of sickle cell disease in a rural hospital of central India, Indian Pediatrics, 2000;37: 391-396.
3. Ahmed SG, Bukar AA,Jolayemi B Hematological Indices of Sickle Cell Tuberculosis in Northern Nigeria. Medit J Hemat Infect Dis 2010;Vol2(1):1-5
4. Omoti CE Haematological Values In Sickle Cell Anaemia In Steady State And During Vaso- Occlusive Crisis In Benin City, Nigeria Annals of African Medicine, 2005: Vol. 4(2); 62 – 67
5. Chikhlikar K,Wilkinson A A Study of Red Cell Parameters in Patients of Sickle Cell Trait IOSR Journal of Dental and Medical Sciences,2014; Vol.13(3):PP 46-50
6. Tedder TF, Steeber DA, Chen A, Engel P. The selectins: vascular adhesion molecules.FACEB J, 1995Vol; 9(10):866-73.

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL

JALGAON, DIST. JALGAON. 425309 MAHARASHTRA

OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology

Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.**

2. **Name of the Principal Investigator**
   Dr .Anagha Amale (Chopade), Professor, Pathology Department
   DUPMC, Jalgaon.

3. **Name of the co-investigator**
   Dr. Uditkumar Agrawal, Associate Professor, BiochemistryDepartment, GMC, Khandwa.

4. **i) Signature of Principal investigator** Aparnal .

   ii) Signature of co- investigator/

   iii) Signature of HOD of Principal Investigator (with seal)

Aparnal.

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon (M), Jalgaon

(For IEC Office use only) **Sr. No**_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) **Place where research work will be carried out**
At DUPMC&H

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and it's analysis:**

3 months.

7) **Risk factor for the patient** (give details): None.

5) **Details about research project-Synopsis Attached**

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

8) **Details of financial burden involved and how it will be met**: Nofinancial burden.

9) **Whether the research project is sponsored**: Yes.
Sponsoring authority: Self.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).

(c) **Case Record Form (CRF)**
(d) Undertaking by the investigator (Appendix VII)
(e) Stability testing of new drug (Appendix IX)
(f) Content of the proposed protocol for conducting clinical trial (Appendix X)
(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)
(h) Study Flow Chart if any.
(i) News paper publication matter for subject recruitment if any.
(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

I the undersigned, Dr Anagha Amale (Chopade) hereby submitting synopsis of my research protocol for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.

Kindly do the needful.

Dr Anagha Amale
(Candidate name and signature)

Dr Anagha Amale
(HOD name and Signature with Dept. seal)

(Guide name and signature)

CASE RECORD FORM

1. Full name of the Subject
2. Age
3. Gender
4. Height
5. Weight
6. Blood Pressure
7. Pulse
8. Pallor
9. Icterus
10. Family History
11. History of Present Illness

12. Any other associated Disorders/Diseases:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled "**Study of Association of E-Selectin, Hematological and Biochemical Parameters in patients of Sickle Cell Disease** ". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled **"Prevalence of Sickle Cell Disorders in patients visited to Tertiary Care Hospital"**. I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Informed Consent Form

I (the undersigned),am willingly ready to participate in the study titled "**Hematological indices, electrolyte status & effect of micronutrients and vitamins on polymerization in sickle cell disease at rural based tertiary care hospital**". I have already been informed fully regarding aims, objectives, study designs, implications and possible side effects of venepuncture. Thus I am ready to give my venous blood sample for fasting blood glucose estimation and my information pertaining to the requirements of the research work.

Name:

Date:

Signature:

Research Protocol

Title of the Research Project: Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.

Introduction: Sickling is accompanied by an intra-erythrocytic loss of potassium and gain of sodium, thus creating disequilibrium in the ionic strength across the cell membrane. Biochemical abnormalities have been associated with sickle cell disease. However, there is a paucity of information on the roles of these ions in the pathogenesis and management of sickle cell disease. Delicate balance of micronutrients and vitamins is required to maintain hydration and membrane integrity.(1-5)

Aim: To find the **Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.**

Objectives: 1.To determine the haematological values & electrolyte status that can be used in monitoring the status and management of sickle cell anaemia patients .

2. To demonstrate in practical terms, the antisickling effectiveness of some micronutrients and vitamins in inhibiting sickle cell hemoglobin polymerization.

Material and methods: Invasive investigations: The parameters will be analyzed in sickle cell patients and controls in a steady state, at DUPMC Hospital, Jalgaon Maharashtra, India. The complete blood counts (CBC) and serum electrolytes will be analyzed and compared.

The antisickling effectiveness of crude extracts of copper, cobalt, magnesium, two fat soluble vitamins(A,E) and one water soluble vitamin (C) will be investigated to ascertain the ability of ions to inhibit sickle cell hemoglobin polymerisation process. Mineral samples of concentration 1.0x10-1 mM, Vitamin A of concentration100 IU and 1 mg/ml for each of vitamins C and E will be prepared and HbSS polymerization experiment will be carried out. Data will be analyzed using SPSS version 20.0. P value $\leq$ 0.05 will be considered to be significant.

Study type: Prospective study

Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

Conflict of interest: None

Risk factors: None

Bibliography/List of references:

1. Meshram AW, Bhatkulkar PA, Khare R, Pazare K. Haematological indices & electrolyte status in sickle cell disease at rural hospital of Central Maharashtra. Int J Med Sci Public Health 2014;3:1410-1412.

2. Bunn, H. F., and Forget, B. G. (1986) Hemoglobin: Molecular, Genetic and Clinical Aspects, Saunders, Philadelphia, 2 –Serjant, G. R. (1992) Sickle Cell Disease, OUP, Oxford.

3. Francis, R. B., and Johnson, C. S. (1991) Vascular occlusion in sickle cell disease: current concepts and unanswered questions. Blood **77,** 1405–1414.

4. Malik P (1999). Nutrition and hematopoiesis: An overview. Workshop on Nutrient Metabolism in genetic Anemias, NHLBI, May 24-25, Bethesda MD.USA.

5. Al-Saqladi AWM, Cipolotti R, Fijnvandraat K, Brabin BJ. Growth and nutritional status of children with homozygous sickle cell disease. Annals of Tropical Paediatrics: International Child Health. 2008;28:165–189. doi: 10.1179/146532808x335624.

Appendix II

INSTITUTIONAL ETHICS COMMITTEE

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL
JALGAON, DIST. JALGAON. 425309 MAHARASHTRA
OFFICE: Member Secretory-IEC, Professor, Dept. of Pharmacology
Phone. No. (Office) 0257-2366657 (Fax) 0257-2366648 Website. http://www.dupmc.ac.in/

APPLICATION FORM FOR PERMISSION (ETHICAL CLEARANCE)

OF RESEARCH PROJECT (BIOMEDICAL RESEARCH ON HUMAN)

N.B.:* To be submitted in TRIPLICATE. One copy will be returned to the department after approval.

(*To be preserved by IEC for minimum 15 years.)

1. **Title of the Research Project: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.**

2. **Name of the Principal Investigator**
   Dr .Anagha Amale (Chopade), Professor, Pathology Department
   DUPMC, Jalgaon.

3. **Name of the co-investigator**
   Dr. Uditkumar Agrawal, Associate Professor, BiochemistryDepartment, GMC, Khandwa.

4. **i) Signature of Principal investigator** dpamale .

   ii) Signature of co- investigator/

   iii) Signature of HOD of Principal Investigator (with seal)

dpamale .
Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

(For IEC Office use only) Sr. No_____

Dept.....

1) Date of Receipt by IEC (submission of application) ----------
2) Date of resubmission to IEC ----------
3) Date of IEC meeting ----------
4) Decision of IEC: APPROVED/ RESUBMISSION/ REJECTED.
5) IEC decision conveyed on date: ----------

CHAIRPERSON
I.E.C.

MEMBER SECRETARY
I.E.C.

5) **Place where research work will be carried out**
At DUPMC&H

(DUPMC&H – Dr. Ulhas Patil Medical College & Hospital)

6) **Time period required for completion of research project and it's analysis:**

3 months.

7) **Risk factor for the patient** (give details): None.

5) **Details about research project-Synopsis Attached**

(a) Objectives:

(b) Current knowledge about the research subject:

(c) Research plan:

(d) Implications:

(e) Conflict of interest:

(f) Risk factors:

(g) Bibliography/List of references:

8) **Details of financial burden involved and how it will be met**: Nofinancial burden.

9) **Whether the research project is sponsored**: Yes.
Sponsoring authority: Self.

Enclosures:

- 4 copies of research protocol (on A-4 size paper only) with appendices (As per Schedule Y of Drugs & Cosmetics Act) should be enclosed i.e. detailed information about investigational products.

(a) Patient information sheet.

(b) Informed consent form for subject participating in clinical trial (in English/Marathi/Hindi) (appendix V).

(c) **Case Record Form (CRF)**

(d) Undertaking by the investigator (Appendix VII)

(e) Stability testing of new drug (Appendix IX)

(f) Content of the proposed protocol for conducting clinical trial (Appendix X)

(g) Data elements for reporting Serious ADR/ADE occurring in clinical trial. (Appendix XI)

(h) Study Flow Chart if any.

(i) News paper publication matter for subject recruitment if any.

(j) Funding details of sponsor or permission letter of other institutions if any, regulatory clearance like DCGI/FDA approval for drugs not marketed in India, ICMR approval for global multi-centric trial.

(Strike out which is not enclosed).

I declare that I shall follow National and International Good Clinical Practice (GCP) guidelines in conducting the above clinical research project.

Signature of Principal Investigator.

Professor & HOD
Dept. of Pathology
Dr. Ulhas Patil Medical College & Hospital
Jalgaon Kh, Jalgaon

1) Principal Investigator should be prepared to give 10 minutes presentation on OHP/Power point to IEC when called.
2) Involved Traditional Medicine Doctor as Co-investigator for research on Traditional Medicine.

Appendix III

Through Proper Channel Only

To
The Chairperson,
IEC DUPMCH,
Jalgaon.

Sub: Submission of Synopsis of research protocol for Ethical Clearance.

I the undersigned, Dr Anagha Amale (Chopade) hereby submitting synopsis of my research protocol for ethical clearance. Kindly consider it for approval from ethics committee.

I am submitting herewith Title of Synopsis as mentioned below & as suggested by my aforesaid Guide.

Title of Synopsis: PREVALENCE OF SICKLE CELL DISORDERS IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.

Kindly do the needful.

Dr Anagha Amale
(Candidate name and signature)

(Guide name and signature)

Dr Anagha Amale
(HOD name and Signature with Dept. seal)

Research Protocol

Title of the Research Project: Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.

Introduction: Sickling is accompanied by an intra-erythrocytic loss of potassium and gain of sodium, thus creating disequilibrium in the ionic strength across the cell membrane. Biochemical abnormalities have been associated with sickle cell disease. However, there is a paucity of information on the roles of these ions in the pathogenesis and management of sickle cell disease. Delicate balance of micronutrients and vitamins is required to maintain hydration and membrane integrity.(1-5)

Aim: To find the **Haematological indices ,electrolyte status & effect of micronutrients and vitamins on polymerisation in sickle cell disease at rural based tertiary care hospital.**

Objectives: 1.To determine the haematological values & electrolyte status that can be used in monitoring the status and management of sickle cell anaemia patients .

2. To demonstrate in practical terms, the antisickling effectiveness of some micronutrients and vitamins in inhibiting sickle cell hemoglobin polymerization.

Material and methods: Invasive investigations: The parameters will be analyzed in sickle cell patients and controls in a steady state, at DUPMC Hospital, Jalgaon Maharashtra, India. The complete blood counts (CBC) and serum electrolytes will be analyzed and compared.

The antisickling effectiveness of crude extracts of copper, cobalt, magnesium, two fat soluble vitamins(A,E) and one water soluble vitamin (C) will be investigated to ascertain the ability of ions to inhibit sickle cell hemoglobin polymerisation process. Mineral samples of concentration 1.0x10-1 mM, Vitamin A of concentration100 IU and 1 mg/ml for each of vitamins C and E will be prepared and HbSS polymerization experiment will be carried out. Data will be analyzed using SPSS version 20.0. P value $\leq$ 0.05 will be considered to be significant.

Study type: Prospective study

Study duration: 3 months

Place of study: DUPMC hospital

Statistical Analysis: SPSS version 20.

Implications: Early assessment of risk of hemolysis with the evaluation of routine parameters. Better services will be timely provided to the patients.

Conflict of interest: None

Risk factors: None

Bibliography/List of references:

1. Meshram AW, Bhatkulkar PA, Khare R, Pazare K. Haematological indices & electrolyte status in sickle cell disease at rural hospital of Central Maharashtra. Int J Med Sci Public Health 2014;3:1410-1412.

2. Bunn, H. F., and Forget, B. G. (1986) Hemoglobin: Molecular, Genetic and Clinical Aspects, Saunders, Philadelphia, 2 –Serjant, G. R. (1992) Sickle Cell Disease, OUP, Oxford.

3. Francis, R. B., and Johnson, C. S. (1991) Vascular occlusion in sickle cell disease: current concepts and unanswered questions. Blood **77,** 1405–1414.

4. Malik P (1999). Nutrition and hematopoiesis: An overview. Workshop on Nutrient Metabolism in genetic Anemias, NHLBI, May 24-25, Bethesda MD.USA.

5. Al-Saqladi AWM, Cipolotti R, Fijnvandraat K, Brabin BJ. Growth and nutritional status of children with homozygous sickle cell disease. Annals of Tropical Paediatrics: International Child Health. 2008;28:165–189. doi: 10.1179/146532808x335624.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 15/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three Orthopedics, two Skin and one Chest and TB PGs-

1	DR. JANBANDHU RAHUL SHANTILAL	COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF FIXATION BY OPEN AND CLOSED METHODS IN DISTAL END RADIUS FRACTURE IN TERTIARY CARE HOSPITAL.
2	DR. PATIL PARIKSHIT PRATAP	TO STUDY FUNCTIONAL OUTCOME OF SURGICAL DECOMPRESSION IN LUMBAR SPINAL STENOSIS IN A RURAL HOSPITAL
3	DR. VELANKAR SUNEET NITIN	STUDY ON EFFICACY AND FUNCTIONAL OUTCOME OF AUTOLOGOUS PLATELET RICH PLASMA INJECTION IN ADHESIVE CAPSULITIS, LATERAL EPICONDYLITIS AND PLANTAR FASCIITIS.
4	DR. KALBANDE PRAJAKTA PRAKASH	STUDY OF VARIOUS CLINICAL PATTERNS OF ADVERSE CUTANEOUS DRUG REACTIONS AT DERMATOLOGY OUT PATIENT DEPARTMENT IN A TERTIARY CARE CENTRE
5	DR. SHAIKH MUBINA IRFAN	CLINICO EPIDEMIOLOGICAL STUDY OF HERPES ZOSTER AND POST HERPETIC NEURALGIA AND ITS IMPACT ON QUALITY OF LIFE
6	DR. SAMADHAN DATTATRAYA BAHEKAR	STUDY OF POST COVID 19 PULMONARY COMPLICATIONS AT A TERTIARY CARE CENTER - PROSPECTIVE OBSERVATIONAL STUDY.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 13/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three Radiology, two Psychiatry and one Chest and TB PGs-

1	DR. BHARAPURIA KANISHKA RAVI	STUDY OF VARIOUS PATTERNS MANIFESTED BY COVID 19 INFECTION ON CHEST CT SCAN AND IMPORTANCE OF EARLY CHEST CT SCAN IN COVID 19 IN TERTIARY CARE HOSPITAL.
2	DR. BHOSALE ABHIJEET DNYANESHWAR	TO STUDY THE ROLE OF MAGNETIC RESONANCE IMAGING IN DIAGNOSIS OF SPINE DISORDERS IN FARM WORKERS ATTENDING TERTIARY CARE HOSPITAL IN JALGAON KH.
3	DR. SHEIKH MOHAMMAD ZAINUL	TO STUDY THE ROLE OF ULTRASONOGRAPHY IN THE DIAGNOSIS OF BLEEDING PER VAGINUM, IN THE FIRST TRIMESTER OF PREGNANCY.
4	DR. SHAIKH MUJAHID KHADARSAB	A STUDY OF ASSOCIATION OF SERUM MAGNESIUM LEVELS WITH THE SEVERITY OF ALCOHOL WITHDRAWAL SYNDROME IN HOSPITALISED PATIENTS IN A TERTIARY CARE HOSPITAL.
5	DR. YADAV GOVIND UDHAVRAO	STUDY OF PREVALENCE AND CHARACTERIZATION OF DEPRESSION IN SCHIZOPHRENIA IN A TERTIARY CARE CENTER.
6	DR. LANGADE SUSHIL SURESH	THE STUDY OF CORRELATION OF C- REACTIVE PROTEIN , LACTATE DEHYDROGENASE, SERUM FERRITIN AND D - DIMER WITH CT SCORE OF COVID PATIETS AND OUTCOME IN DEDICATED COVID HOSPITAL

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 11/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of three Ophthalmology and two ENT PGs-

1	Dr. AKASH UTTAMRAO MALVI	A STUDY TO EVALUATE AND COMPARE VISUAL OUTCOMES AFTER CATARACT SURGERY IN DIABETICS COMPARED TO NONDIABETIC PATIENTS AT A TERTIARY CARE CENTRE.
2	Dr. ANUJA VINAYAK GADGIL	A CLINICAL STUDY OF SUTURELESS GLUEFREE CONJUNCTIVAL AUTOGRAFT REPAIR IN PTERYGIUM SURGERY.
3	Dr. DESHMUKH KALPANA ARJUNRAO	STUDY OF EFFECT OF MYOPIA AND AXIAL LENGTH ON PERIPAPILLARY RETINAL NERVE FIBRE LAYER USING SPECTRAL DOMAIN OPTICAL COHERENT TOMOGRAPHY
4	Dr. HARSHAL VASUDEO MAHAJAN	A COMPARATIVE STUDY OF ENDOSCOPIC SEPTOPLASTY OVER CONVENTIONAL SEPTOPLASTY IN TERTIARY CARE CENTER.
5	Dr. KHANDAGALE SHRUTI SHAILENDRA	A COMPARATIVE STUDY BETWEEN GRAFTS OF TRAGAL CARTILAGE, TEMPORALIS FASCIA LATA IN PATIENTS POSTED FOR REVISION TYMPANOPLASTY.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 08/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

4.1 To discuss the research study of **Dr. Anagha Amale (Prof. Department of Pathology, DUPMCH) and Dr. Uditkumar Agrawal (Associate Professor, Biochemistry Department, GMC Khandwa)**

I. **PREVALENCE OF SICKLE CELL DISORDER IN PATIENTS VISITED TO TERTIARY CARE HOSPITAL.**

II. **STUDY OF ASSOCIATION OF E-SELECTIN AND HEMATOLOGICAL PARAMETERS IN PATIENTS OF SICKLE CELL DISEASE**

III. **HEMATOLOGICAL INDICES, ELECTROLYTE STATUS AND EFFECT OF MICRONUTRIENTS AND VITAMINS ON POLYMERIZATION IN SICKLE CELL DISEASE AT RURAL BASED TERTIARY CARE HOSPITAL.**

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2021. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr Devendra R. Chaudhari.

Member Secretary

DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 07/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of Anesthesia and Pathology PGs-

1	Dr. DESHPANDE HARSHA SANJAY	TO STUDY THE EFFECT OF INTRAVENOUS MAGNESIUM SULPHATE IN ATTENUATING THE HEMODYNAMIC RESPONSE DURING LARYNGOSCOPY AND INTUBATION IN PATIENTS REQUIRING GENERAL ANAESTHESIA AT A TERTIARY CARE CENTRE.
2	Dr. KELGAONKAR VIJAYA VIVEK	A COMPARATIVE STUDY OF DEXAMETHASONE AS AN ADJUVANT TO LOCAL ANAESTHETIC DRUG FOR SUPRACLAVICULAR BLOCK WITH PLACEBO IN A TERTIARY CARE CENTER
3	Dr. PRAJAKTA PRAKASH SHILAHAR	COMPARATIVE STUDY BETWEEN FENTANYL AND BUPRENORPHINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRA UMBILICAL SURGERIES
4	Dr. SONONE SHIVAJI DILIP	TO COMPARE EFFECT OF 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB SURGERIES IN TERTIARY CARE CENTRE.
5	Dr. KAMBLE PRIYANKA SHASHIKANT	THE STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY OF HEAD AND NECK REGION LYMPHADENOPATHY WITH ITS HISTOPATHOLOGIC CORRELATION IN TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ **Minutes of Meeting**

DATE: 04/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of Surgery PGs-

1	Dr. ANISH AVINASH JOSHI	COMPARATIVE STUDY OF EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA WITH SALINE DRESSING IN DIABETIC FOOT ULCER BY EXAMINING NEOVASCULARIZATION ON BIOPSY
2	Dr. FARKE VAIBHAV BALASAHEB	STUDY OF ETIOLOGY AND MANAGEMENT OF PERITONITIS AT TERTIARY CARE HOSPITAL
3	Dr. MANKAR SHUBHAM SHRIKRUSHNA	SPECTRUM OF DISEASES MANAGED BY LAPAROSCOPY AND ITS OUTCOME AT TERTIARY CARE CENTRE
4	Dr. SHRIYASH KONDIBA SONAWANE	STUDY OF MANAGEMENT AND OUTCOME OF ACUTE OBSTRUCTIVE UROPATHY DUE TO CALCULUS IN A TERTIARY CARE CENTRE
5	Dr. SIRPURAM VARUNDEV ASHOK	EFFECT OF FLAP FIXATION TECHNIQUE ON SEROMA FORMATION AND ITS COMPLICATIONS IN PATIENTS UNDERGOING BREAST CANCER SURGERY AT A TERTIARY CARE CENTER.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2021/ Minutes of Meeting

DATE: 02/01/2021
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Devendra R. Chaudhari	Member Secretary	
3.	Dr. (Mrs) Maya N. Arvikar	Member	
4.	Dr. Amrut Mahajan	Member	
5.	Dr. Milind P. Joshi	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 09.00 am

Meeting Actual Start: 09.05 pm

4 AGENDA

4.1 To discuss the research study of medicine PGs-

1	**Dr. KAMELI MOHAMMAD JUNAID RAFEEQUE AHMAD**	COMPARATIVE STUDY OF ECG AND CORONARY ANGIOGRAPHIC FINDINGS WITH ACUTE CORONARY SYNDROME IN DIABETIC AND NON-DIABETIC PATIENTS IN TERTIARY CARE CENTRE
2	**Dr. KOTECHA TEJAS KUNDAN**	STUDY OF CLINICAL PROFILE OF PATIENTS WITH HYPONATREMIA IN TERTIARY CARE HOSPITAL
3	**Dr. NANDEDKAR ADITYA MAHADEV**	THE STUDY OF SERUM MAGNESIUM AND VITAMIN D3 IN TYPE 2 DIABETES MELLITUS AND ITS CORRELATION WITH CORONARY ARTERY DISEASE
4	**Dr. PRIYANKA ASHOK BHALKE**	BACTERIAL SPECTRUM OF ASCITIC FLUID IN ALCOHOLIC LIVER DISEASE PATIENT ON ADMISSION AND ITS CORRELATION WITH SERUM ASCITIC ALBUMIN GRADIENT.
5	**Dr. WAGAJ SUSHANT PRAKASH**	A STUDY TO ESTIMATE PREVALENCE OF ANAEMIA IN ACUTE AND CHRONIC INFLAMMATION IN PATIENTS ATTENDING TERTIARY CARE HOSPITAL.

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from JANUARY 2021 to APRIL 2022. The implication of the study assets the improvement in student's performance after assignment given to them.
3. It was ensured that study was undertaken as per IEC guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

MEETING SCHEDULE END: 12.30 PM

Meeting Actual End: 12.50 pm

Dr Devendra R. Chaudhari.
Member Secretary
DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 30/12/2020

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 02/01/20021 to 15/01/2021 from attached circular at 9.00 am

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Devendra R. Chaudhari
3	Dr. (Mrs) Maya N. Arvikar
4	Dr. Amrut Mahajan
5	Dr. Milind P. Joshi
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366646 E-Mail Id : dupmcj@yahoo.in

DATE - **24/12/2020**

Circular

For all PG students and PG guides

All PG students are requested to present their thesis topic in front of IEC, DUPMCH, Jalgaon, in PPT format initially on flowing respective dates to finalize the topic.

All PG guides of respective department must attend the session on respective dates of presentation. After that the final submission will be taken in proper protocol format.

Time table is as follows...

TIMING – 2 TO 4 PM

SN	Department	Date
1	Medicine (5)PGs	02/01/2021
2	Surgery (5) PGs	04/01/2021
3	Anesthesia (4) & Pathology (1) PGs	07/01/2021
4	OBGY (3) & Pediatrics (2) PGs	08/01/2021
5	Ophthalmology (3) & ENT (2) PGs	11/01/2021
6	Radiology (3), Psychiatry (2) & Chest TB (any one out of TWO) PGs	13/01/2021
7	Skin (2), Ortho (3) & Chest TB (remaining one PG) PGs	15/01/2021

Shot on realme C2
By Rahul Bhavasar

Dean
DUPMCH, JALGAON

4 AGENDA

To discuss the research study of 3RD YR STUDENT **Mr. Sumit Sudhir Masne**

"UTILIZATION OF MENTAL HEALTH SERVICES AMONG LGBTQIA + COMMUNITY IN INDIA: A MULTISTAKEHOLDER ENPOWERING QUALITATIVE APPROCH"

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from March 2022 to July 2022.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmci@yahoo.in

Date:- 12/02/2022

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 14/02/2022 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2022/ Minutes of Meeting

DATE: 14/02/2022
Location:
Dean's Office
Recorded by: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2	Dr. Rahul Prakash Bhavasar	Member Secretary	
2.	Dr. Shubhangi D. Chaudhari	Member	
3.	Dr. Vaishali Nagose	Member	
4.	Dr. Shivaji Sadulwad	Member	
5.	Dr. Nilesh Bendale	Member	
6.	Adv. Satish Gadge	Member	
7.	Dr. Prashant S. Warke	Member	
8.	Prof. Girish A. Kulkarni	Member	
9.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 02.00 pm

Meeting Actual Start: 02.05 pm

4 AGENDA

To discuss the research studies of second year MBBS **students who has sent the topics for ICMR project.**

Project no	Name of the student	Project name	Guide name
3	Ms. Anushka Ananda Khavare *IInd year MBBS Student*	"CHANGE IN ATTITUDE AND PERSPECTIVE TOWARDS VACCINATION IN HEALTH CARE PROFESSIONALS OF TERTIARY CARE HOSPITAL AFTER DECREASE IN SEVERITY OF COVID 19 STRAIN IN COUNTRY."	Dr. Rahul Prakash Bhavasar.
4	Ms. *Anchal Devendra Pal* *IInd year MBBS Student*	"ANALYSIS OF PRESCRIPTION PATTERN IN EMERGENCY UNIT ATTENDING TERTIARY CARE HOSPITAL."	Dr. Suyog Chopade.
5	Mr. Charoushya Bharat Pandya *IInd year MBBS Student*	"CLINICAL AND MICROBIOLOGUCAL PROFILE OF URINARY TRACT INFECTION IN HAEMODIALYSIS PATIENT ATTENDING TERTIARY HEALTH CARE FACILITY."	Dr. Kailas Wagh
6	Ms. Aamina Niyaz Baig. *IInd year MBBS Student*	"UTILITY OF CULTURE AND ANTIBIOTIC SENSITIVITY TEST FOR ADMITTED PATIENTS IN AN ATTEMPT TO COMBAT INCREASING ANTIMICROBIAL RESISTANCE IN A TERTIARY CARE HOSPITAL."	Mr. Prashant Kumar Guddeti
7	Ms. Shivani Choudhary. *IInd year MBBS Student*	"WILLINGNESS AND ABILITY OF UNDERGRADUATE MEDICAL SCHOOL STUDENTS TO PERFORM A BYSTANDER CPR AFTER BLS TRAINING".	Dr. Devendra R. Chaudhari.
8	Ms. Meera Laxman Survase. *IInd year MBBS Student*	"STUDY THE CONTAMINATION OF 'KHADI SAAKHAR' BY COLIFORM BACTERIA *ESCHERICHIA COLI* SERVED IN HOTELS AND RESTAURANTS"	Dr. Jayant Mahadeorao Deshmukh
9	Ms. Ruchira Shashikant Kaole. IInd year MBBS Student	"SERO-PREVALENCE OF TRANSFUSION TRANSMISSIBLE INFECTIONS AMONG BLOOD DONORS AT A TERTIARY CARE CENTER IN JALGAON"	Dr. Vipin Narendra Todase
10	Ms. Shilpa Vallabh Senta. IInd year MBBS Student	"KNOWLEDGE, AWARENESS, AND PRACTICE OF SCREENING OF CERVICAL CANCER AMONG WOMEN IN A RURAL POPULATION AND TERTIARY HEALTH CARE CENTRE"	Dr. Shubhangi Devendra Chaudhari
11	Ms. Rupali Pandurang Totewad. IInd year MBBS Student	"ANTHROPOMETRIC ASSESSMENT OF NUTRITIONAL STATUS OF NEONATES APPROACHING TO NICU AT TERTIARY CARE HOSPITAL."	Dr. Nilesh Prakash Bendale

4.1

Minutes of meeting:-

1. As Dr. Rahul Bhavasar an actual member secretory of IEC, DUPMCH himself was acting as Guide, Chairman – Dr. Parag Patil had appointed Dr. Nilesh Bendale as member secretory for this meeting and had submitted conflict of interest form to Dr. Parag Patil sir.

2. IEC Members Dr. Nilesh Bendale and Dr. Shubhangi Chaudhari also submitted conflict of interest form to Dr. Parag Patil sir as they also acted as guide to two of the student.
3. So during discussion of the respective topics IEC members who acted as guide for that topic had not participated during taking the decision of approval.
4. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
5. The study will be conducted by them from May 2022 to July 2022.
6. It was ensured that study was undertaken as per ICE guidelines.
7. The permission was granted to conduct the study by the committee members.
8. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 05.00 pm

Meeting Actual End: 5.50 pm

IEC.DUPMCH.JALGAON

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 02/02/2022

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 04/02/2022 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2022/ Minutes of Meeting

DATE: 04/02/2022
Location:
Dean's Office
Recorded By: Dr. Shubhangi D C.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	Dr. Shubhangi D. Chaudhari	Member Secretary	
3.	Dr. Vaishali Nagose	Member	
4.	Dr. Shivaji Sadulwad	Member	
5.	Dr. Nilesh Bendale	Member	
6.	Adv. Satish Gadge	Member	
7.	Dr. Prashant S. Warke	Member	
8.	Prof. Girish A. Kulkarni	Member	
9.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4 AGENDA

To discuss the research study of 3RD YR STUDENT **Priyanka Pandya**

"QUARANTINE MYOPIA: AN EPIDEMIC EMERGING AMIDST COVID -19 PANDEMIC OWING TO "NEW-NORMAL" ENVIRONMENTAL RISK FACTORS AMONG MEDICAL STUDENTS OF MAHARASHTRA - A CROSS – SECTIONAL QUESTIONNAIRE BASED STUDY"

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them from February 2022 to July 2022.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.30 pm

Meeting Actual End: 4.50 pm

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax : [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648
Date:- 22/01/2022

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 24/01/2022 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2022/ Minutes of Meeting

DATE: 24/01/2022
Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 26/04/2022

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 28/04/2022 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2022/ Minutes of Meeting

DATE: 28/04/2022
Location:
Dean's Office
Recorded by: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2	Dr. Rahul Prakash Bhavasar	Member Secretary	
2.	Dr. Shubhangi D. Chaudhari	Member	
3.	Dr. Vaishali Nagose	Member	
4.	Dr. Shivaji Sadulwad	Member	
5.	Dr. Nilesh Bendale	Member	
6.	Adv. Satish Gadge	Member	
7.	Dr. Prashant S. Warke	Member	
8.	Prof. Girish A. Kulkarni	Member	
9.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 02.00 pm

Meeting Actual Start: 02.05 pm

4 AGENDA

To discuss the research studies of PATHOLOGY PG **student and Assistant Professor Physiology.**

Project no	Name of the student	Project name
12	DR. PRIYANKA S KAMBALE	"APPLICATION OF SYDNEY SYSTEM GUIDELINES FOR REPORTING LYMPHNODE FINE NEEDLE ASPIRATION CYTOLOGY: A EXPERIENCE AT INSTITUTIONAL LEVEL,"
13	DR. ALOK KUMAR YADAV	"STUDY TO ASSES PULMONARY RESPONSE OF DIFFERENT GRADES OF EXERCISE BY USING TRAIDMILL AND ERGOMETRY BICYCLE IN YOUNG ADULT,"

4.1

Minutes of meeting:-

1. Topic of research study was discussed under – title of the study, aims and objectives of the study, research plan and methodology, questionnaire, inclusion and exclusion criteria, interpretation of data, implications, risk factors, references, any sponsorship by the committee members.
2. The study will be conducted by them within a year duration.
3. It was ensured that study was undertaken as per ICE guidelines.
4. The permission was granted to conduct the study by the committee members.
5. Application form for permission of research project was duly signed by Chairperson and Member secretary.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 05.00 pm

Meeting Actual End: 5.50 pm

IEC,DUPMCH,JALGAON

Dr. Rahul Prakash Bhavasar.
Member Secretary
DUPMCH

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 23/02/2022

CIRCULAR

All members of Institutional Ethics committee are informed that meeting is arranged in Dean's office on 24/02/2022 from attached circular at 3.00 pm

All members are requested to attend meeting

Copy to all members

Sr No	Name
1	Dr. Parag R. Patil
2	Dr. Rahul P. Bhavasar
3	Dr. Shubhangi D. Chaudhari
4	Dr. Vaishali Nagose
5	Dr. Shivaji Sadulwad
6	Dr. Nilesh Bendale
7	Adv. Satish Gadge
8	Dr. Prashant S. Warke
9	Prof. Girish A. Kulkarni
10	Mrs. Swara J. Waghodkar.

Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon
kh.

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
INSTITUTIONAL ETHICS COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

IEC/ 2022/ Minutes of Meeting

DATE: 24/02/2022
Location:
Dean's Office
Recorded By: Dr. Rahul P. B.

1 MEETING ATTENDED BY

Sr. No.	Member Name	Designation	Signature
1.	Dr. Parag R. Patil	Chairman	
2.	DR. Rahul Prakash Bhavasar	Member Secretary	
3.	Dr. Shubhangi D. Chaudhari	Member	
4.	Dr. Vaishali Nagose	Member	
5.	Dr. Shivaji Sadulwad	Member	
6.	Dr. Nilesh Bendale	Member	
7.	Adv. Satish Gadge	Member	
8.	Dr. Prashant S. Warke	Member	
9.	Prof. Girish A. Kulkarni	Member	
10.	Mrs. Swara J. Waghodkar.	Member	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-14.10.2016

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr.No.	Member Name	Designation
1.	Dr. Ravindrakumar. L. Bakal	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. (Mrs) Maya N. Arvikar	Member
4.	**Dr. Amrut Mahajan**	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Smita C. Pathade	Member
7.	Dr. Rahul P. Bhavasar	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10.	Mr. Prabhakar. M. Jangale	Member
11.	Mr. Sandesh Y. Patil	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-08.09.2017

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr.No.	Member Name	Designation
1.	Dr. Ravindrakumar. L. Bakal	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. (Mrs) Maya N. Arvikar	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Smita C. Pathade	Member
7.	**Mr. Bapurao M. Bite**	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10.	Mr. Prabhakar. M. Jangale	Member
11.	Mr. Sandesh Y. Patil	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-14.02.2019

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr. No.	Member Name	Designation
1.	Dr. Ravindrakumar. L. Bakal	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. (Mrs) Maya N. Arvikar	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	**Dr. Nilesh P. Bendale**	Member
7.	Mr. Bapurao M. Bite	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10.	Mr. Prabhakar. M. Jangale	Member
11.	Mr. Sandesh Y. Patil	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-15.04.2019

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr. No.	Member Name	Designation
1.	Dr. Ravindrakumar. L. Bakal	Chairman
2.	Dr. Devendra R. Chaudhari	Member Secretary
3.	Dr. (Mrs) Maya N. Arvikar	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Nilesh P. Bendale	Member
7.	**Dr. Rahul P. Bhavasar**	Member
8.	Adv. Satish Gadge	Member
9.	Dr. Prashant S. Warke	Member
10.	Mr. Prabhakar. M. Jangale	Member
11.	Mr. Sandesh Y. Patil	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-22.12.2020

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr. No.	Member Name	Designation
1.	Dr. Parag R. Patil	Chairman
2.	**Dr. Devendra R. Chaudhari**	Member Secretary
3.	**Dr. (Mrs) Maya N. Arvikar**	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Nilesh Bendale	Member
7.	Adv. Satish Gadge	Member
8.	Dr. Prashant S. Warke	Member
9.	Prof. Girish A. Kulkarni	Member
10.	Mrs. Swara J. Waghodkar.	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-20.08.2021

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr. No.	Member Name	Designation
1.	Dr. Parag R. Patil	Chairman
2.	**Dr. Rahul P. Bhavasar**	Member Secretary
3.	**Dr. Shubhangi D. chaudhari**	Member
4.	Dr. Amrut Mahajan	Member
5.	Dr. Milind P. Joshi	Member
6.	Dr. Nilesh Bendale	Member
7.	Adv. Satish Gadge	Member
8.	Dr. Prashant S. Warke	Member
9.	Prof. Girish A. Kulkarni	Member
10.	Mrs. Swara J. Waghodkar.	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date :-29.09.2021

INSTITUTIONAL ETHICS COMMITTEE COMPOSITION

Sr. No.	Member Name	Designation
1.	**Dr. Parag R. Patil**	Chairman
2.	**Dr. Rahul Prakash Bhavasar.**	Member Secretary
3.	**Dr. Shubhangi D. Chaudhari**	Member
4.	**Dr. Vaishali Nagose**	Member
5.	**Dr. Shivaji Sadulwad**	Member
6.	**Dr. Nilesh Bendale**	Member
7.	**Adv. Satish Gadge**	Member
8.	**Dr. Prashant S. Warke**	Member
9.	**Prof. Girish A. Kulkarni**	Member
10.	**Mrs. Swara J. Waghodkar.**	Member

Dean

Dr Ulhas Patil Medical College
& Hospital Jalgaon kh

File No. ECR/1417/Ulhas/Inst/MH/2016

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 30/09/2016

To,

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

Subject: Ethics Committee Registration No. **ECR/852/Inst/MH/2016** issued under Rule 122DD of the Drugs & Cosmetics Rules1945

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the registration of Ethics Committee.

Your Ethics Committee is hereby registered under Rule 122DD vide Registration No. **ECR/852/Inst/MH/2016** with the following composition and all the condition mentioned under the Registration certificate issued to you.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Ravindrakumar L. Bakal	M.Pharm, PhD	Chairman
2.	Dr. Devendra R. Chaudhari	MD (Pharmacology)	Member Secretary
3.	Dr. Maya N. Arvikar	MD (Obst & Gyane)	Clinician
4.	Dr. Milind P. Joshi	MCH, Pediatric Surgery	Clinician
5.	Dr. Rahul P. Bhavasar	MD (Pharmacology)	Basic Medical Scientist
6.	Dr. Sandeep V. Pakhale	MS (Anatomy)	Basic Medical Scientist
7.	Dr. Smita C. Pathade	MD (Pathology)	Basic Medical Scientist
8.	Adv. Satish G. Gadge	LLM	Legal Expert
9.	Mr. Prabhakar M. Jangale	MA, B.Ed	Lay Person
10.	Dr. Prashant S. Warke	BE, MBA (Marketing), PhD (Business Adm.)	Social Scientist
11.	Mr. Sandesh Yashwant Patil	12th Pass	Non Scientific Member

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority

Dte. General of Health Services
Ministry of Health & F.W.
FDA Bhawan

File No. ECR/1417/Ulhas/Inst/MH/2016

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 30/09/2016

To

The Chairman,
Institutional Ethics Committee,
Dr. Ulhas Patil Medical College & Hospital,
1st Floor, College Building, DUPMCH,
Jalgaon-425309, Maharashtra,
India.

SUB: - Ethics Committee Registration No. **ECR/852/Inst/MH/2016** issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Sir/Madam,

Please refer to your application no. Nil dated 09.03.2016 submitted to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the **INSTITUTIONAL ETHICS COMMITTEE,** situated at **DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, 1st FLOOR, COLLEGE BUILDING, DUPMCH, JALGAON-425309, MAHARASHTRA, INDIA** with Registration number **ECR/852/Inst/MH/2016** as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. This Registration is subject to the conditions specified under Rule 122DD and Appendix VIII of Schedule-Y of Drugs and Cosmetics Act, 1940 and Rules 1945.
2. The Ethics Committee shall review and accord its approval to a clinical trial at appropriate intervals as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well-being of the trial subjects.
3. In the case of any serious adverse event occurring to the clinical trial subjects during the clinical trial, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.
6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

Dr Ulhas Patil Medical College
and Hospital, Jalgaon Kh.
Inward No.: 248
Date: 10 / 10 / 2016

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non-Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions of clinical trials under this Schedule, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    I. Basic medical scientist (preferably one pharmacologist)
    II. Clinician
    III. Legal expert
    IV. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    V. Lay person from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/submission by you that yours is an Institution and registration is sought for Institutional Ethics Committee.

(Dr. G. N. Singh)
Drugs Controller General (I) & Licensing Authority

Drugs Controller General (I)
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

SOP MANUAL
INSTITUTIONAL ETHICS COMMITTEE, DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL, JALGAON KHURD, 425309

Standard Operating Procedures-Manual
SOP Title: Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd, Standard Operating Procedure (IEC, DUPMCH, SOP) SOP Authors: IEC, DUPMC, Members

SOP Status: Current
Version No and Date: 3 and Date: 28th Oct 2021 Validity: 3 year from the Date or till next revision Compiled by: Dr. Rahul Prakash Bhavasar, Member Secretary
Reviewed by: All committee members

Approved by: Chairperson: Dr. Parag Patil.
Fee Structure of Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd (IEC, DUPMCH)

Fees for Protocol Review and Approval:

Particulars	Fees (INR)
Submission for Clinical Trials for IEC review	75,000+GST
Submission of Amendments of Approved Protocols for IEC review	30,000+GST
Extraordinary Submission for Clinical Trial for expedited(fast-track) IEC review	1,00,000+GST
Extraordinary Submission of Amendments of Approved Protocols for expedited(fast-track) IEC review	60,000+GST
Annual Renewal of Clinical Trial Approval by IEC	25,000+GST
Submission for Serious Adverse Event for approved Clinical Trials	35,000+ GST

The IEC, DUPMCH reserves all rights to waive these fees or change this amount without any prior notice to anyone except the committee members.

Payee Name: DR. ULHAS PATIL MEDICAL COLLEGE

PANCARD NO – AAATG1840Q

Index

1. OBJECTIVE....8
2. AUTHORITY FOR CONSTITUTION OF ETHICS COMMITTEE 8
3. FUNCTIONS OF INSTITUTIONAL ETHICS COMMITTEE (IEC)....9
4. HRRP CONSTITUTED UNDER IEC AND ITS PURVIEW ….....10
5. PROTOCOL FOR UPDATION OF STANDARD OPERATING PROCEDURE.....11

a. Amendment Request or Preparation of New SOP:....11
b. SOP Subcommittee....12
c. Review of the draft SOP and submission of final draft SOP 12
d. Approval of New/revised SOP 12
e. Implementation, Distribution and Filing of the SOPs 13
f. Manage and Archive Previous Versions of SOPs 13

6. COMPOSITION OF IEC, DUPMCH.... 13
7. ADMINISTRATIVE SUPPORT 22
Duties of the Administrative Staff.... 23
8. APPLICATION PROCEDURE 24
For Biomedical and Health Research....24
For Clinical Research 25
9. ESSENTIAL DOCUMENTS TO BE SUBMITTED FOR REVIEW....26
I. Documentation Required For Biomedical and Health Research.... 26
II. Minimum documentation required for Clinical Trials....27
10. REVIEW OF PROPOSAL....28
11. EXPEDITED REVIEW AND EXEMPTION FROM FULL REVIEW.... 31
EXPEDITED REVIEW 31
EXEMPTION FROM FULL REVIEW....32
12. AMENDMENTS TO PROTOCOL AND THEIR APPROVAL....33

13. ELEMENTS OFREVIEW 35
Protocol 36
Informed Consent Form and Participant Information Sheet.....36
Advertisement 39

Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device /Collaborative Trials 37

14. CONDUCT OF MEETING 40

Before Meeting 41
Conduct of Meeting.....42
After the Meeting 43

15. DECISIONS MAKING AND POST MEETING ACTIVITIES 44
16. MONITORING 46
Site Monitoring Visit 46
Continuing Review of Study Protocols.....48
Adverse Events and Serious Adverse Event Monitoring 49
Protocol Deviations/Violations..... 52
17. SUB-COMMITTEE(S) OF IEC..... 54
18. PRINCIPAL INVESTIGATOR'S RESPONSIBILITY.....55
19. RECORD KEEPING AND ARCHIVING 57

ANNEXURE 1: ACADEMIC RESEARCH PROPSALSUMMARY SHEET.....60

AND CHECKLIST FOR RESEARCH PROPOSAL SUBMISSION.....62
ANNEXURE 2: FORMULATION OF NEW SOP/REVISIONOFSOP.....63
ANNEXURE 3: INSTITUTIONALETHICS COMMITTEE.....64
MEMBERSHIP LIST w.e.f 29th Sept2021.....64

ANNEXURE4:CONFIDENTIALITY AGREEMENT FORM FOR INDEPENDENT CONSULTANTS 66

ANNEXURE 5: ONE PAGE CV FORMAT FOR IECMEMBERS/INVESTIGATORS ….67
ANNEXURE 6: CONFIDENTIALITY AND CONFLICTOFINTEREST.....68
AGREEMENT FORM.....68
ANNEXURE 7:VOTING REFERENCE 71

ANNEXURE 8: STANDARD OPERATIVE PROCEDURE (SOP) FOR SPECIAL/VULNERABLE POPULATIONS 72

ANNEXURE 9: IEC REVIEW CHECKLIST 80

ANNEXURE 10: CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING CLINICAL TRIALS 82

ANNEXURE 11: ELEMENTS OF THE INFORMED CONSENT 88

ANNEXURE 12: STUDY MONITORING VISIT REPORT FORM 92

ANNEXURE 13: FORMULA FOR QUANTUM OF COMPENSATION 96

IN CASE OF SERIOUS ADVERSE EVENTS 96

ANNEXURE 14: STUDY PROGRESS REPORT 100

ANNEXURE 15: CONFLICT OF INTEREST DISCLOSURE FORM 103

ANNEXURE 16: IEC SELF-ASSESSMENT FORMAT 106

ANNEXURE 17: CHECKLIST FOR CLINICAL TRIAL DOCUMENTS SUBMITTED FOR IEC REVIEW 108

ANNEXURE 18: TEMPLATE FOR INFORMED CONSENT DOCUMENT FOR PARTICIPANTS' PARENTS FOR RESEARCH INVOLVING CHILDREN/MINORS....110

ANNEXURE 19: TEMPLATE FOR INFORMED ASSENT DOCUMENT FOR RESEARCH INVOLVING CHILDREN/MINORS 113

ABBREVIATIONS ……..118

STANDARD OPERATING PROCEDURE (SOP) OF IEC, DUPMCH

Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital (IEC, DUPMCH) intends to review and oversee the conduct of biomedical and health research as well as clinical trial research. The IEC, DUPMCH is constituted in accordance with and ensures its compliance to the ethical guidelines of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, New Drugs and Clinical Trials Rules dated 19 March 2019, ICH-GCP, the Indian Council of Medical Research (ICMR) and functions in accordance with said guidelines and it is conducted in Dr. Ulhas Patil Medical College and Hospital, JALGAON and all constituent colleges.

1. OBJECTIVE

The objective of Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital (hereinafter referred to "IEC, DUPMCH") of Dr. Ulhas Patil Medical College and Hospital (hereinafter referred to "DUPMCH") is to

1. Ensure ethical review of research protocol and the conduct of research at DUPMCH affiliated institutes which involves human participation.
2. Safeguard the safety, dignity, and welfare, including privacy and confidentiality, of the participants involved in the research study directly or indirectly.
3. Ensure that all biomedical research are as per ethical guidelines
4. Provide periodic review of ethical decision taken for all research proposals to ensure the quality, consistency and its adherence to the applicable ethical guidelines.

2. AUTHORITY FOR CONSTITUTION OF ETHICS COMMITTEE

The DEAN, DUPMCH shall constitute the Institutional Ethics Committee, in consultation with the Director of DUPMCH, Registrar of DUPMCH, Chairperson and the Member Secretory of IEC, DUPMCH.

3. FUNCTIONS OF INSTITUTIONAL ETHICS COMMITTEE (IEC)

- To provide independent, comprehensive and timely reviews of the ethics of proposed studies before the commencement of a study and regularly monitor the ongoing studies.
- IEC will review and approve all research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of research participants irrespective of the source of funding.
- The goals of research, however important, should never be permitted to override the health and well being of the research participants.
- The IEC will ensure that all the cardinal principles of research ethics viz, autonomy, beneficence, Non-malfeasance and justice are taken care of in planning, conduct and reporting of a proposed study. It will look into the aspects of informed consent process, risk benefit ratio, distribution of burden/benefit and provisions for appropriate compensations wherever required.
- It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through final report and site visits if required.
- The committee will also ensure compliance with all regulatory requirements, applicable guidelines and laws.
- The ethics committee should exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study, e.g., members of a group with hierarchical structure (e.g. prisoners armed forces personnel, staff and students of medical, nursing and pharmacy academic institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or other incapable of personally giving consent.
- Ethics committee should get documented "standard operating procedures" and should maintain a record of its proceedings.

- Ethics committee should indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licensing Authority.
- Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licensing Authority.

4. HUMAN RESEARCH REVIEW PANEL (HRRP) CONSTITUTED UNDER IEC, DUPMCH AND ITS PURVIEW

IEC, DUPMCH is considered as the apex body for ethical aspect of research serving to following FOUR constituent Institutes of Godavari Foundation.

A. Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd
B. Godavari College of Nursing
C. Dr. Ulhas Patil College of Physiotherapy
D. Dr. Ulhas Patil Homeopathic Medical College and Hospital

The IEC has constituted Human Research Review Panels (HRRP) at each constituent college/department, which will facilitate the functioning of IEC. The HRRP will function as the first window for accepting applications of all Biomedical and Health Research synopses in the prescribed format (Refer Annexure 1) except for the clinical trial synopsis (protocols) which will be accepted directly at the IEC, DUPMCH secretariat office.

HRRP will review the submitted proposals and provide its comments to IEC, DUPMCH. The HRRP will also facilitate the IEC, DUPMCH by giving their opinion on the level of risk of the submitted protocols; comments on the submitted synopses, give a regular follow-up report on the ongoing studies and all submission related documents will be filed by the HRRP office for records.

HRRP shall consist of 4 to 20 members of respective college experts. They will review both the students' "and faculties' "research projects. Those research studies which involve the new drug or technology use, new indication, company sponsored trials; PhD studies etc will be discussed in full board ethics committee meeting only. In case of studies involving high risk, HRRP will forward it to IEC, DUPMCH after due technical review and along with comments for full board ethics committee review.

The HRRP will not, in any form, give any approvals or certificates with respect to the research submissions.

5. PROTOCOL FOR UPDATION OF STANDARD OPERATING PROCEDURE:

The SOP covers the procedure of writing, reviewing, distributing and amending SOPs within the IEC, DUPMCH. The IEC, DUPMCH updates its own Standard Operating Procedures based on applicable regulatory guidelines.

a. Amendment Requestor Preparation of New SOP:

IEC, DUPMCH updates SOP, whenever new Regulations or any Amendments from Central Regulatory Board have been received, any member of the IEC, Secretariat, administrative staff, investigator or authority can make a request for revision or on noticing an inconsistency/discrepancy or has any suggestions can put forth his/her request by using the request application (Refer Annexure2).

Among any of the above Mentioned case, discussion shall be done amongst the IEC, DUPMCH members in meeting. Upon agreeing of the members to this request, Chairman will appoint a SOP Subcommittee for the changes in the SOP as per requisition. If majority of IEC members do not agree to the request, no further action will be taken. Chairperson will inform the member who made the request in writing about the decision. In any case, final decision whether or not to form the subcommittee will be of the Chairperson.

b. SOP Subcommittee

The Chairperson will establish an SOP subcommittee having thorough knowledge about the scientific and ethical review process which includes member secretary, 1 or 2 member and administrative staff. SOP team may carry out writing the procedure of IEC or make the changes requested. The draft SOP will be formulated by SOP team.

c. Review of the draft SOP and submission of final draft SOP

The Draft SOP will be reviewed by the all EC members. If any comment or suggestion will be incorporated and final approval will be taken in EC meeting.

d. Approval of New / Revised SOP

The Final SOP will be signed by Member Secretary and Chairperson IEC, DUPMCH, which then will be forwarded to authority of the DUPMCH and regulatory authorities. The date of approval is the effective date of implementing the SOP.

e. Implementation, Distribution and Filing of the SOPs

The date of approval is the effective date of implementing the SOP. The Approved SOPs will be notified to the licensing authority of India. These SOPs will be circulated amongst the member of the EC, administrative staff, DUPMCH authority, HRRPs of respective institutes and the Investigators. A log will be maintained for the recipient of SOP by IEC, DUPMCH office. The

Original Set of the SOP will be maintained in the SOP master file for record. The paper photocopies of the same will be valid for official use, only with the dated signature of the member secretary.

f. Manage and Archive Previous Versions of SOPs

Previous versions of SOPs will be retained and clearly marked "Superseded" and archived in a file by the Member Secretary/Administrative staff at the archival room of the IEC, DUPMCH.

6. COMPOSITION OF IEC, DUPMCH

The Purpose of IEC, DUPMCH is to have uniformity in the Ethical Review process and to critically analyze the Scientific and Ethical concerns associated with the research submissions in either of these forms:

1. Post Graduate Dissertations/research studies
2. UG Student Research Project
3. Faculty Research Projects
4. Sponsored Clinical Trial Protocols.
5. Any other biomedical and health research involving human participants

IEC, DUPMCHs shall be multi disciplinary and multi-sectoral in composition. The number of members in the committee shall be at least 7. The external members shall be present to ensure the independence of the committee. The Chairperson of the committee shall be from outside and non- affiliated with the Institution. Moreover, The Co-Chairperson (Co-chair) would be appointed which would act as decision authority in absence of the Chairperson. She/he shall also not be affiliated with the institution.

The Member Secretary shall be nominated from the members of the DUPMCH itself. The member secretary shall conduct the administrative duties of the ethics committee. Other members will represent different specialties from medical and non-medical background to reflect the different viewpoints. The composition of the IEC, DUPMCH shall be as follows,

1. Chairperson (Non Affiliated with the DUPMCH)
2. Basic medical scientist/Scientists
3. Clinician/Clinicians
4. Legal expert
5. Social scientist/representative of non-governmental voluntary agency
6. Layperson from the community(Non-affiliated with the DUPMCH)
7. Member-Secretary (Drawn from the Institute)

IEC, DUPMCH shall also have members from other institutions from constitutional institutes of DUPMCH. There shall be an adequate representation of age, gender, community etc. in the committee to safeguard the interests and welfare of all sections of the society. The Committee shall have at least one women representation. (Refer Annexure 3 for updated IEC, DUPMCH composition). The Ethics Committee referred consists of at least fifty percent of its members who are not affiliated with the institute or organization.

a) Independent Consultants

IEC, DUPMCH will call upon Subject experts as consultants for review of selected research protocols. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. cancer patients, HIV/AIDS positive persons or ethnic minorities. Subject experts shall not have voting rights. Confidentiality agreement (Refer Annexure 4) must be signed by them regarding the meeting and the protocols deliberations.

b) Secretariat

The Secretariat consists of the Member Secretary and administrative staff/support staff. The administrative staff shall be appointed by the institute as per university rules and regulations.

c) Membership

The DEAN, DUPMCH will appoint the Chairperson, IEC and the member Secretary in consultation with DIRECTOR, DUPMCH. All the members of IEC will be appointed by the Dean in consultation with the Chairperson and member Secretary. CV of all members will be collected in a single format. (Refer Annexure 5) IEC, DUPMCH will inform to licensing authority of India about the constitution of IEC or about the changes in membership list if any.

d) Appointment

The selection of EC member shall be based on the qualification and experience, Ethical & Scientific knowledge, Interest, Commitment & availability, willingness to provide unbiased opinion etc. Members representing as medical Scientist or clinician should have post graduate qualification and adequate experience in their respective field. There should not be any conflict of interest while making an appointment. Directors, Head of Institutions, Superintendents and authority of university will not serve as a member.

e) Terms of Office, Renewal, Resignation or Termination of membership

The duration of the membership will be for a minimum of period of 5 years. The membership shall be renewed after the stated term. There will be no bar on the members serving for more than one term but it is desirable to have around one third new members during the reconstitution. A member who wishes to resign should provide a written notification of their proposed resignation date to the Chairperson of IEC, DUPMCH or Dean, DUPMCH. A new member can be appointed of the same category (For e.g. If Legal advisor resigns then the new legal expert

should be appointed) by the Dean, DUPMCH in consultation with Chairperson and Member Secretary.

A member can be replaced in the event of long-term non- availability (three consecutive meetings). Letter of Termination will be provided to the member. Authority to replace the member shall remain with the Chairperson of IEC, DUPMCH. University authorities shall be informed about this termination and it should be documented in the minutes of next duly constituted IEC meeting.

Any changes in terms of membership i.e. Resignation/Termination shall be notified in written to the licensing Authority of India.

f) Roles and Responsibilities of IEC, DUPMCH

The Prime responsibility of IEC, DUPMCH is to determine the Scientific and ethical aspects of Research Proposals and ensuring the protection of rights, safety and well being of the research participants. The committee shall;

- Provide independent and competent review of all ethical aspects of research proposals within stipulated time frame.
- Ensure to safeguard the dignity, rights, safety and well being of all study participants. Special consideration to be ensured in reviewing the protocols involving vulnerable population.
- Scientific aspects of the research proposal shall be evaluated.
- Review progress report and monitor ongoing studies.
- Evaluate the suitability of the Investigator in terms of qualification, training and experience as documented in CV for the proposed study.
- Review and revise SOP from time to time as per SOP.
- Maintain confidentiality of the study documents and deliberation of the IEC meeting.
- Monitor SAEs, protocol deviations & violations and recommend appropriate actions.

- Shall actively participate in educational training program and remain trained & updated on the regulatory requirement.

Chairperson will be responsible for

- Chairing the meeting and accountable for independent and efficient functioning of the committee
- Seeking Conflict of Interest (CoI) declaration from members and ensure quorum and fair decision making.
- Ensuring active participation of all members in all discussion and deliberations.
- Appointing new members and forming subcommittees for any task.
- Facilitating IEC educational activities and keeping abreast the regulation and policies governing review of research projects involving human subjects.
- Handling of complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

Member Secretary and the Secretariat will be responsible for the following

- Effective and Streamlined process of receipt, preparation, circulation and handling of each proposal for review.
- Arranging/Scheduling IEC, DUPMCH meetings on regular basis(once in three months and/or as and when required)
- Communication of IEC members with Investigators, Chairperson and with Regulatory Authority
- SOP update as and when required.
- Completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
- Review and Recommendations for expedited review/ exemption from review or full review of submitted synopses/protocols.
- Maintaining the financial records of IEC.
- Making pre and post arrangements of IEC meeting.

- Assess the need and recommendations to obtain prior scientific review, invite independent consultant, patient or community representatives.
- Ensure quorum during the meeting and record discussions and decisions taken in form of minutes.
- Filing study related documents i.e., Archiving and maintaining the study files.

`Other IEC, DUPMCH Members` will represent appropriate balance of professional, ethical, legal, cultural, clinical and community interest. Their Primary responsibility will be of determining the Scientific and Ethical Validity of the research and the protection of the safety, rights, well being & confidentiality of the research subject.

`Basic Medical Scientist` will be preferably a pharmacologist as IEC, DUPMCH reviews clinical trials with drugs as well as biomedical and health research involving human participants and will be responsible for:

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- For clinical trials, biomedical and health research involving human participants, pharmacologist to review the drug safety and pharmacodynamics.

`The Clinician` will be an individual with recognized medical qualification, expertise and training and will be responsible for

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics.
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report).
- Review medical care, facility and appropriateness of the principal investigator, provision for medical care management and compensation.

- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

`The Legal Expert` will be an individual having basic degree in law from a recognized university, with experience.

- He/she will be involved in ethical review of proposal, ICD along with translations, MoU (Memorandum of Understanding), Clinical Trial Agreement (CTA), regulatory approval, Insurance document, other site approvals, researcher's undertaking, protocol specific other permission if any.
- `The Social Scientist` will be any individual with social/ behavioural science /philosophy /religious qualification and training and/or expertise and be sensitive to local cultural and moral values. She/he may be from an NGO involved in health-related activities
- Ethical review of the proposal, ICD along with the translations.
- Assess impact on community involvement socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal /community representative and bring in ethical and societal concerns.

`The Lay person` can be any literate person from the public or community has not pursued a medical science/ health related career in the last 5 year and is aware of the local language, cultural and moral values of the community. She/he shall be responsible for:

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects if any.

g) Training

Training on the ethical aspects of health-related research with human participants and on the IEC, DUPMCH SOP shall be imparted to the IEC members when they join and periodically during their committee service. Member secretary shall be responsible for providing training to the new members.

The revised/amended IEC, DUPMCH SOP training shall be given by the member secretary/other member of the SOP team to rest of the IEC Members before the new IEC, DUPMCH SOP comes into enforcement. The IEC shall conduct workshops from time to time to impart training to the IEC members and Institutional faculty members.

h) Conflict of Interest and Confidentiality

- It shall be declared by the IEC, DUPMCH members at the first meeting that there is no direct conflict of interest, possible conflicts of interest that may compromise his/her position on the IEC by signing the conflict of interest (CoI) form (Refer Annexure 6). If a member has direct conflict of interest with a proposal being considered shall not be a part of the quorum.
- There should not be any undue influence of the members by the way of their institution association, financial liability, kinship or authority in their decision.
- The member having conflict of interest with any of the proposals for review in the meeting will disclose it before the meeting and will fill the Conflict of Interest Disclosure Form (Refer Annexure15).
- All the IEC, DUPMCH members should maintain absolute confidentiality of all discussions during the Meeting, including the documents circulated for review, unless required by law.
- It is responsibility of each IEC, DUPMCH member to read, understand, accept and sign the Confidentiality Agreement (Refer Annexure 6) regarding meeting deliberations, applications, information on research participants and

- related matters at the beginning of the tenure of his/her membership and the term of which shall be binding on them even after the termination of the contract.
- These signed confidentiality and conflict of interest forms will be filed in a separate file by IEC, DUPMCH secretariat.

i) Quorum Requirement for Meeting

The full board meeting will be held as scheduled for clinical trial review provided there is quorum. A minimum of 5 members shall be required for a quorum representing the following background:

- Basic Medical scientist(preferably a pharmacologist)
- Clinician
- Legal expert
- Layperson
- Social scientist or representative of Non-governmental voluntary agency All decisions shall be taken in meetings and not by circulation of project proposals.

j) Schedule of Meeting

IEC, DUPMCH shall meet regularly at least once in three months; however, the frequency of IEC meeting shall be based on the number and the type of protocols eg. Clinical trial or Biomedical and health research to be reviewed.

k) Honorarium to the Members/Independent Consultants

Honorarium for attending IEC, DUPMCH meetings shall be given to the IEC, DUPMCH members as per financial policy of IEC, DUPMCH. Reimbursement of travelling expense and/or honoraria may be given to Independent consultant and any other person authorized by the IEC, DUPMCH.

1) Evaluation of IEC/Chairperson/Member Secretary/Members/IEC Staff- Self- assessment

The committee will carry out periodic self-assessment once a year.

The member/s and administrative staff will be designated by Chairpersons for carrying out self assessment. The corrective and preventive actions (as required) will be discussed in the full board meeting and will be implemented accordingly (Refer Annexure 16) Annual Self Evaluation of Chairperson will be done.

Annual Evaluation of IEC, DUPMCH members/ Member Secretary will be done by Chairperson. The individual feedback will be provided by email to the members.

7. ADMINISTRATIVE SUPPORT:

To support the smooth functioning of the IEC, DUPMCH, the administrative staff shall be appointed by the Head of the Institute. The Secretariat of IEC, DUPMCH includes the Member Secretary of IEC, DUPMCH and the support staff.

IEC, DUPMCH makes certain that the support staff is adequate in numbers and trained enough to enable the IEC, DUPMCH to carry out its technical and administrative responsibilities.

Adequate resources will be provided to support staff to fulfill its assigned functions including office space, and equipment and supplies. (e.g. computers, stationery, telephones, photocopies, shredding machine etc.)

The supporting staff will assist the member secretary in executing functions of the IEC and it consists of the staff members of DUPMCH appointed by the DEAN of DUPMCH. Additional supporting staff may be appointed as per requirement after discussion amongst the IEC, DUPMCH members.

Duties of the Administrative Staff:

- Establish an effective and smooth handling procedure for each proposal received at IEC, DUPMCH Secretariat. This includes its receipt; register entry, circulation for further review and storage management.
- Assisting Member secretary in organizing IEC, DUPMCH meetings regularly, in preparation of the agenda and minutes of meetings.
- Maintaining IEC, DUPMCH records and archives.
- Communicating with IEC, DUPMCH members and Principal Investigator.
- Assisting Member Secretary in arranging training for Faculty, PG students of DUPMCH and IEC, DUPMCH members.
- Providing necessary administrative support for IEC, DUPMCH related activities to the Member Secretary, IEC, DUPMCH.
- Receiving IEC, DUPMCH processing fees and forwarding to Account Department of DUPMCH and receiving and maintaining official receipts for the same.
- Corresponding with the IEC, DUPMCH members, external experts and investigators.
- Making the pre and post arrangements of IEC, DUPMCH meetings.
- Filing study related documents.
- Assisting in preparation for accreditation and audits of IEC, DUPMCH
- Participate in the development and subsequent implementation of SOPs

All the communications between the IEC and Investigator/Institution/Regulatory Authority will be from and through the member Secretary/Chairperson of IEC, DUPMCH.

The Secretariat of IEC, DUPMCH will receive protocols for review/notification/request from Students, Faculties and Principal Investigator of DUPMCH and then will circulate amongst the IEC, DUPMCH members.

Any Decision made regarding the study (Approval/Rejection/Query response requested) shall be communicated from Member Secretary on behalf IEC, DUPMCH to the respected applicant/applicants.

Correspondence Regulatory agencies will be carried out through Chairperson/Member Secretary of the IEC, DUPMCH.

8. APPLICATION PROCEDURE

For Biomedical and Health Research:

The following procedure will be followed by the Students and Faculties of DUPMCH for submission of the Research Proposals.

- Research Proposals along with the relevant documents shall be submitted along with an Application Form in the prescribed format (Refer Annexure 1) and addressed to Chairperson/Member Secretary of IEC, DUPMCH.
- The Application shall first be addressed to the HRRP (Human Research Review Panel) Coordinator of the concerned college/department of DUPMCH which will serve as a first window for accepting all the research proposals from students/faculties of their college/department. HRRP will acknowledge the receipt and indicate any lacunae. Re-submission in case of missing information/clarification requested shall be done within two weeks.
- The HRRP will Review the Research Proposal and shall provide their Opinion/Comments and then forward the same to member secretary of IEC, DUPMCH.
- The IEC, DUPMCH will acknowledge the receipt of the application with supporting annexure.
- IEC, DUPMCH shall review the Research Proposal received and then either Approves/Rejects the Proposal or raises the queries to the Investigator. The decision of the IEC, DUPMCH shall then be communicated through HRRP to the applicant in writing.

For Clinical Research:

- All the Research Proposal shall be addressed to the Chairperson of the IEC, DUPMCH, and shall be submitted to the Member Secretary/Secretariat.
- Member Secretary/Secretariat will ensure the completeness of the submission against the checklist for Clinical Trial Documents and to IEC, DUPMCH (Refer Annexure 17) and then will provide the applicant, the acknowledgement receipt (Signed, Stamped and dated) for the submitted documents.
- In case of incomplete submission or in case if additional documents required, member secretary will inform PI to re-submit missing document or to submit additional document required. Member Secretary will reconfirm the completeness with the prior submission and updates the submission accordingly.
- Total 10 hard copies and One(1) soft copy of the study documents shall be submitted to the IEC, DUPMCH. The number of hardcopies to be submitted may vary depending on number of members in EC constitution.
- Application shall be made along with the prescribed fees for the review of proposal. (New Protocol/Amendment/Expedited Review)
- As per IEC, DUPMCH, the Fees will be accepted as cheque /demand draft drawn in favor of "DR. ULHAS PATIL MEDICAL COLLEGE".
- A unique submission number shall be assigned to each proposal submitted for review.
- Submission shall be done at minimum 3 weeks prior to the next IEC, DUPMCH meeting.
- Investigator shall be notified in writing to be present for a scheduled IEC, DUPMCH meeting to present their protocol and offer clarification if any required during the meeting.
- In case of any Amendment PI should submit one (1) hard copy of the amended documents highlighting the modification/s in the amendment along with summary of changes. The member secretary in consultation with Chairperson will decide whether to carry out Expedited Review or request Notification in case minor administrative changes.

- In case of requirement of full board review, PI should submit 10 hard copies of the amended documents along with the prescribed EC fees to IEC, DUPMCH.

9. ESSENTIAL DOCUMENTS TO BE SUBMITTED FOR REVIEW

All research proposals including clinical trials shall be submitted minimum 3 weeks before the upcoming IEC, DUPMCH meeting with the following documents.

I. Documentation Required For Biomedical and health Research:

- Cover letter to Member Secretary
- Application Form (Annexure – 1)
- Title of the project (Cover Page -Title of the Proposal, Name & Sign of the PI and Co-I with Designation, Name of any other Institute/Hospital/Field area where research will be conducted)
- Names of the PI and Co-investigators with designation.
- Name of any other Institute/Hospital/Field area where research will be conducted.
- Approval of the Head of the Department.
- Protocol of the proposed research
- Ethical issues in the study and proposed measures to address these issues.
- Proposal shall be submitted with all relevant Annexure like proforma, Case Record Forms, Questionnaires, follow-up cards, etc. to be used in the study.
- Participant Information Sheet and Informed Consent Form in vernacular language(s) should be enclosed. The consent form shall be as per new drugs and CT rules2019.
- For any drug/device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country/other countries, if available.

- Any regulatory clearances required. Copy of clearances if obtained. This will be necessary for New drug/device not approved for marketing in India, justification for sending of biological samples outside India and use of radioactive pharmaceuticals in clinical studies.
- Source of funding and budget along with the supporting documents.
- Indemnity issues including insurance certificate for the compensation to the participants etc, if applicable.
- Statement of conflicts of interest, if any.
- Plans for publication of results-positive or negative-while maintaining the privacy and Confidentiality of the study participants.
- Any other information relevant to the study.

II. Minimum documentation required for Clinical Trials

Ten (10) sets of hard copy and one (1) soft copy of the following documents have to be submitted along with continuous pagination i.e. for every new document, corresponding page numbering should start from where it ended for the previous document and not as page no. one (1).

a) Cover letter to Member Secretary
b) Final Version of Protocol of the proposed research.
c) Investigator Brochure (IB) (as applicable for drug/biological/clinical trials)
d) The Final Version of Patient Information Sheet (PIS) and Informed Consent Form (ICF) in English, Hindi and Marathi along with a translation certificate and Back translation certificate wherever applicable.
e) Final Version of Case Record Form(CRF)
f) Recruitment Procedure; advertisement, notices (if applicable)
g) Patient Instruction card, diary, etc. (if applicable)

h) Insurance Certificate for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage risk or Indemnification policy document (if applicable).
i) Acknowledgement and/or Permission letter from licensing authority to conduct clinical trial
j) Any other regulatory permissions(As applicable)
k) Final Version of Clinical Trial Agreement (CTA)/Clinical Study Agreement (CSA)
l) Undertaking by the Investigator
m) Principal Investigator's current CV, MRC and GCP training certificate duly signed and dated.
n) Clinical Trial Registry – India (CTRI) Registration Certificate

10. REVIEW OF PROPOSAL

The member secretary shall screen the proposal for the risk associated with the study depending upon the risk, as defined in "New Drugs and Clinical Trial Rules 2019" involved in the research proposal, the member secretary shall subject them to: Full Board Review, Expedited Review and Exemption from Review.

All research involving the following will be subjected to Full Board Review:

- Research involving more than minimal risk.
- Proposals/Protocols which do not qualify for exempted or expedited review.
- Projects involving vulnerable population such as children, prisoners, pregnant women, mentally disabled persons, or other special groups.

The foremost task of the IEC is to review the study proposal and supporting documents giving importance to its scientific validity, ethical issues and submission form for suitability and feasibility of the study. The IEC, DUPMCH will analyze and take into the consideration the following criteria to ensure the ethical basis of review of the submitted protocol.

1. Risk Factors, Adequacy against Risks & Potential Benefits:

It should be taken care that the subject participating in the research that bear the risk of participation shall be benefited out of research directly or out of new knowledge that the research is designed to yield. IEC members should be aware that risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration.

IEC, DUPMCH Members shall ensure that Research is scientifically sound and valid because if the research is not scientifically valid then it exposes research participants and their communities to risks or harm without possibility of benefit.

2. Recruitment & Withdrawal of Subject(s):

Recruitment strategies shall describe the purpose of the research, the risk and potential benefits of participating in the research and other relevant details. Patient's participation in the study should be voluntarily. It has to be checked there is no influencing factor for the patient's participation in the study. It is to be ensured that patient can willingly withdraw the consent with prior intimation. This should not affect his/her further routine medical treatment.

3. Access to personal data:

Access of personal data of the research participants, including medical records, source data and biological samples shall remain with the Principal Investigator and supporting Staff. With Permission of the PI, the regulatory authorities/Ethics committee can have access to these data for Audit/Monitoring purpose.

4.Investigator's Qualification:

IEC, DUPMCH shall ensure the required qualification and experience of the investigators and adequacy of the site for the proposed study.

5. Data and Safety Monitoring for the Clinical Trials and biomedical and health research:

IEC, DUPMCH will monitor the ongoing studies at site continually for ensuring compliance to study protocol. This includes review of the overall progress of each study to insure safety of the study participants, validity of the data, evaluating the risks and adverse events, reporting of the adverse events to the appropriate agencies. IEC, DUPMCH shall make a visit in case of reporting of adverse events or violation of human rights.

6. Financial benefits and Costs to Research Subjects:

Subject shall be reimbursed for any cost associated with participation in the study, including transportation, child care or lost wages. However, the payments shall not be high enough that will eventually influence the subject to participate in the research.

7. Serious Adverse Events Monitoring:

IEC, DUPMCH ensures the provisions are made for compensation/treatment and reporting of the events done by Investigator in the case of injury/disability/death of a research participants as per existing national legislation (CDSCO).

8. Complaint/Query by the Research Participants:

Member Secretary/Administrative staff upon receipt of the query/complaint records it in a register and informs the Chairperson. Chairperson along with member secretary will investigate the details to determine the truth and individual perception. Chairperson may even be able to consider the matter for full board review and appoint a sub-committee for enquiry. The final decision shall be informed to research participants by the secretariat.

Elements of Review are further described in this SOP.

11. EXPEDITED REVIEW AND EXEMPTION FROM FULL REVIEW

EXPEDITED REVIEW

Virtual or Tele/Video conference should be attempted to ensure social distancing as face-to-face meetings may not be suitable. Use virtual software platform (Zoom, google meet) preferably a video

National Guidelines For EC Reviewing Biomedical & Health Research During Covid -19 Pandemic ICMR APRIL 2020)

Proposals which are recommended for minor revisions will be reviewed by a subcommittee or Member Secretary for clearance and will be approved by the Chairperson/Member Secretary.

The approvals will be reported in the next IEC meeting by Member Secretary. The revised form of proposals requiring major changes will be reviewed in the next ethics committee meeting.

If Sponsor of Clinical Research intends Research Proposal (Initial/amendment) to be reviewed before 15 days then this will be considered as Extraordinary Submission and applicable fees will need to be paid for this fast track review process by the Sponsor.

EXEMPTION FROM FULL REVIEW

The criteria for exemption include those considered as “minimal risk” suggested by the ICMR Guidelines, 2017. Exemption from review may be granted to proposals which satisfy one of the following conditions:

Exemption 1: Research conducted in an established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement); survey/interview procedures; observation of public behavior,unless:

(i) Informationobtainedisrecordedinsuchamannerthathumansubjectscanbeidentified Directly or through identifiers linked to the subjects and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption 4: Research and demonstration projects that are conducted by or subject to the approval of heads of Government departments or agencies and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programmes (ii) procedures for obtaining benefits or services under those programmes (iii) possible changes in or alternatives to those programmes or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programmes.

* Research involving Vulnerable Population (For SOP for Vulnerable/Special Population – Refer Annexure 8) will not be considered for exemption from review.

Procedure for Exemption from Full Ethics Review:

It is the responsibility of PI to apply for research proposal for approval to HRRP. HRRP based on above criteria will take decision on "minimal risk" research proposal. The committee will recommend to IEC, DUPMCH for approval. The IEC, DUPMCH has empowered the member secretary to give approval to such research proposal. All such approvals shall be presented in next ethics committee for information to the committee.

12. AMENDMENTS TO PROTOCOL AND THEIR APPROVAL

Any proposed change or revision to IEC, DUPMCH approved study that affects human participants must be reviewed and approved by the IEC, DUPMCH prior to the implementation of that change. It is the responsibility of the Member Secretary/Chairperson to determine whether the proposed protocol amendment(s) is minor or major in nature. If there is minor amendment of the protocol and related documents, then it will be reviewed by member secretary/Chairperson.

Only administrative changes such as changes in telephone numbers; addition/deletion of staff or Investigators; changes in funding, alteration of the project title; typographical error in protocol, etc, do not require approvals, but they must be notified to IEC, DUPMCH.

For major amendment all the changes will be discussed in upcoming IEC, DUPMCH full board meeting.

A change which requires full ethics board review and approval is one which, in the judgment of the IEC reviewer, makes substantial alteration in:

- The level of risks to participants,
- The research design or methodology such as replacement of or significant changes to study instruments including surveys and questionnaires or adding/revising eligibility criteria or changes to the study population
- The number of participants enrolled in the research
- The informed consent to include a newly identified risk related to the study (this may require that participants sign a new consent form)
- The qualifications of the research team
- The facilities available to support safe conduct of the research
- In advertisement
- Addition or deletion of sites (due to non-recruitment or SAE, fraud and misconduct)
- Any other factor, which would warrant review of the proposed changes by the convened IEC. In addition, revised procedures must involve no more than minimal risk

The final decision regarding the amendments shall be informed to the Principal Investigator and the decision can be approved, approved with modification, or not approved.

The PI should highlight the modification/s in the amendment, along with summary of changes.

13. ELEMENTS OF REVIEW

The emphasis should be given on ethical guidance, grounded in the core principles of Respects for person, concern for welfare and justice. The foremost responsibility of the IEC is to review research proposals and their supporting documents with special attention to safety of the participants involved in research. The followings shall be taken into consideration during the review of a Protocol:

- Scientific design and conduct of the study.
- Approval of scientific review committee and regulatory agencies.
- Assessment of predictable risks/harms and potential benefits.
- Procedure for selection of participants including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
- Management of research related injuries, adverse events and compensation provisions.
- Justification for placebo in control arm as well as Placebo arm in the study? If any.
- Availability of products to the trial participants after the study, if applicable.
- Patient information sheet (PIS) and informed consent form (ICF) in English/Hindi and local language
- Protection of privacy and confidentiality of participants.
- Involvement of the community, wherever necessary.
- Protocol and proforma of the study including the consent form (CF).
- Plans for data analysis and reporting.
- Adherence to all regulatory requirements and applicable guidelines.
- Competence of investigators, research and supporting staff.
- Facilities and infrastructure.

Review Checklist (ReferAnnexure9) will be filled by each IEC, DUPMCH member for each clinical trial proposal to be reviewed in the IEC, DUPMCH meeting.

Protocol

The Clinical Research Protocol should be as per New Drug and Clinical Trial Rules dated March 2019 (Refer Annexure 10)

Informed Consent Form and Participant Information Sheet

The IEC, DUPMCH will assess the adequacy of safeguard of the rights and welfare of the research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation criteria to ensure protection of the human subjects participating in the research is well defined in the Review of Proposal of this SOP.

Informed consent is most crucial element of research that needs to be taken care by every investigator participating in the research. “The Voluntary Consent of the human subject is absolutely essential as has been laid down in the Principle of the Nuremberg code. Obtaining consent from Research Participants involves both the consent dialogue and the documented informed consent process on the IEC, DUPMCH approved informed consent forms.

While approving the Patient Information Sheet and the Informed consent Forms, IEC, DUPMCH ensures that the language used is to the level of understanding of the participant, contains all the essential information related to the study, translated documents in are available in Hindi and Marathi language, translation and back translation certificates are available, etc.

Informed consent process should be carried in such a way that the study participant understands each and every aspect and are answered for any & every query they have related to the study. It shall be taken care to use the language that the participants understand. Research participants should be given time as much as is needed by them to reach to the decision of their participation. It shall be taken care to avoid therapeutic misconception where the participants over-estimates the benefits or under-estimates the risk associated with the study which in turn affects their ability to provide voluntary and knowing informed consent.

In case where the subject is not able to provide informed consent (e.g Unconscious person or a minor etc,) all the information related to study shall be provided to the legally acceptable representative. If the subject or his/her LAR is unable to read/write – an Impartial Witness (IW) shall be present during the entire informed consent process.

The required essential documents of informed consent should be discussed with participants using approved ICF. Investigator shall constantly check the level of understanding of the subject asking the open-ended questions which results in obtaining legally effective informed consent document from subject. The copy of the signed ICF shall be given to the patient and the original shall be retained by the Principal Investigator.

IEC, DUPMCH may conduct surprise visit to the Informed consent site when the consenting process is going on by the Investigator. IEC, DUPMCH can also interview the participants to confirm the appropriateness of the Informed consent taken by the investigator.

Informed consent form is revised after assessing the need based on changes to the protocol, events occurring within the study, which increase risk to the study subjects, or as directed by the sponsor. ICF with concerned changes requested by the sponsor and/or investigator, when directed by the IEC, DUPMCH, re-consent the previously enrolled subjects with the revised, EC approved version of the informed consent form.

In case of clinical trials on pediatrics, the subjects are legally unable to provide written informed consent, and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case,

(i) Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.

(ii) Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.

(iii) Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

Essential Elements of Informed Consent Form

A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the informed consent form for trial subject is as per New Clinical Trial Rule, 2019 (Refer Annexure11)

Audio-Video Recording

Audio-visual recording of Informed Consent Process shall only be mandatory for cases where vulnerable population is involved & the trial is of New Chemical Entity or New Molecular Entity. For clinical trials of Anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent Process shall be mandatory. Audio-visual recording can be required as and when required by Ethics Committee.

The Investigator must provide the subject/LAR/IW with the information described in the informed consent section before signing the informed consent by the subject.

The language of information should be non-technical and understandable by the study subjects/ LAR/ IW and the same shall be recorded through audio-visual means. Details of questions if any, asked by the subject/ LAR/ IW and his/her understanding on consent are also to be recorded through the audio video recording. The process of signing/ putting thumb impression by the subject/LAR/IW should also be video recorded.

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible should be kept confidential. The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects.

The trial data of subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

To maintain the confidentiality, the videographer should also be recruited as part of the study team. Prior to initiation of the study, the Investigator should define and allocate the activities of audio- Video recording of informed consent process to the respective identified person as videographer and should be mentioned in the study log of roles and responsibility of research staff.

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial. Audio-visual recording of informed consent process and other related documents should be preserved safely after the completion / termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently.

Proposal involving vulnerable population and special group

(Refer Annexure 8)

Advertisement

EC reviews advertisement to ensure that advertisement do not exaggerate the outcome and benefits than actually mentioned in consent document or protocol, do not emphasize on payment or free treatment, or Include exculpatory language. Example: In the event that you suffer a research- related injury, your medical expenses will be covered by your medical insurance.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as: The name and address of the researcher or research facility, The purpose of the research or the condition under study, In summary form, the criteria that will be used to determine eligibility for the study.

Memorandum of Understanding and Indemnity Agreement for Sponsored Drug/Device/Collaborative Trials

IEC, DUPMCH shall review the Clinical Trial Agreement/Memorandum of Understanding and Indemnity Agreement documents. IEC, DUPMCH shall ensure that the indemnity and compensation are appropriate and as per the applicable standards. It shall be taken care that the drug trial is started only after the agreement is signed by all the concerned parties (PI, Sponsor and HOI).

14. CONDUCT OF MEETING

IEC, DUPMCH meeting shall be conducted at scheduled interval preferably once every three months. However, depending upon the load of the Research Proposal, Meeting can be called upon as and when required. The final IEC, DUPMCH meeting date shall be informed to all the members well in advance to ensure their availability for meeting.

The Secretariat shall be the convener with overall responsibility for organizing the IEC, DUPMCH meeting from preparing agenda to communicating the decision of the IEC to the Investigator.

For the meeting, the following deliberations shall be made, if full quorum is available.

- Declaration of conflict of interest
- Confirmation of Last meeting's minutes
- Action taken for the Last meeting
- Details of risk-benefit assessment decision of review of proposal

- Any changes requested
- Protocol Deviations, Adverse events/SAEs
- Non-Compliance
- Monitoring sites, reports, and Corrective and Preventive action (CAPA) plan; if any,
- Any other relevant discussions/updates

Before Meeting

- Member Secretary will prepare the Agenda of the IEC, DUPMCH meeting.
- The hard copy of the Research Proposals shall be circulated to all members prior to 3 weeks along with the agenda of the meeting and action taken on the previous meeting. Agenda of the meeting will also be sent to all the members via email, if required.
- Member Secretary prior to meeting ensures that there is no conflict of interest with any of the IEC members due to his/her participation in the protocol which are going to be reviewed; If it is found then Secretary will seek the concerned EC member to declare the same in conflict of Interest form (Refer Annexure 15) and then excuse themselves for that particular protocol review and decision making process. In case if quorum requirement is not fulfilling due to the COI of any EC member on the day of IEC, DUPMCH meeting then the meeting will be Re-scheduled or cancelled.
- All the Investigators shall be informed via letter to be present for the meeting to present his/her protocol to the IEC, DUPMCH members.
- All IEC, DUPMCH meetings will be held at the DEAN OFFICE DUPMCH, unless otherwise specified. Good working conditions in the room along with IT and Technical support will be ensured.

Conduct of Meeting

- Members should gather for the meeting on schedule date and time.
- At the beginning of each convened IEC, DUPMCH meeting, the member secretary will discuss and announce to declare if there is any conflict of interest with any of the IEC,

- DUPMCH member and informs that member having a conflict of interest must excuse themselves from deliberations and decision on that research proposal.
- If the unanticipated conflict of interest affects quorum, that particular item will not be discussed and will be deferred to the next scheduled meeting.
- Research involving vulnerable populations will be placed on to the agenda only when at least one individual (IEC member or Independent consultant/subject expert) who is knowledgeable and experienced in working with the population will participate in the meeting.
- Secretariat shall obtain signatures on confidentiality, Conflict of interest, if any, attendance, etc.
- Chairperson will initiate the meeting and secretary shall discuss the minutes of the previous meeting, action taken for the major/pending issues discussed in previous meeting and agenda for the current meeting.
- Principle Investigator shall be invited to present their proposals, and clarify doubts, if any.
- In case the secretary of the IEC, DUPMCH is the Principal Investigator for the project under review, the IEC, DUPMCH member nominated as acting Member Secretary will perform the function of the Secretary only for that study. The secretary should declare his/her conflict of interest and leave the meeting room.
- In Case the lead discussant cannot attend the meeting, the Co-Investigator or Secretary, IEC, DUPMCH or any other member of IEC may brief the IEC, DUPMCH about the research study.
- IEC, DUPMCH will completely review the research studies submitted. The committee will review new studies, amendments, annual/continuing review of ongoing studies, SAE reports, any other documents, and assess final reports of all research activities through a scheduled agenda.
    - The member Secretary, IEC, DUPMCH/ IEC, DUPMCH administrator minutes/records the proceedings of the IEC, DUPMCH meeting.
    - The decision shall only be made at the meetings where a quorum is present

- Only IEC, DUPMCH members who attend meeting will participate in the decision.
- It is the right of IEC member to disagree to approval of proposal. He/she has to give written explanation for disagreement.
- In each decision, voting of members shall be done. Voting Reference sheet (Refer Annexure7) will be kept as an evident of voting of each member. Based on voting the decision shall be taken.

After the Meeting

- The Member Secretary and IEC administrator will compile the meeting proceedings in a concise and easy to read style.
- The minutes will record whether the decision was unanimous, or whether the vote was taken for the decision. The number of members voting for, against and abstaining will be recorded.
- Conflict of interest; if any will also be included in the meeting minutes.
- The basis for requiring changes in or disapproving research; and a written summary of controversial issues and their resolution must be recorded.
- The draft minutes will be finalized by member secretary and will be circulated amongst the other members and Chairperson within a week of the meeting via an email.
- Any comments/changes requested by any member will be discussed /included by the member secretary. The final minutes of meeting will be signed by Member Secretary and Chairperson.
- Original version of the minutes will be placed in the minutes of meeting file
- A copy of decision letter along with all project related correspondence shall be placed in the appropriate project files.
- The Member Secretary shall convey the decision in writing to the Principal Investigator of the study preferably within10 days of the meeting.

15. DECISIONS MAKING AND POST MEETING ACTIVITIES

The IEC, DUPMCH shall provide complete and adequate review and based on that approval of the research Proposals submitted to them. The following points will be considered while doing so:

- An IEC member will withdraw from the meeting for the decision procedure concerning the study where the conflict of interest exists.
- If any IEC member has his/her own proposal for IEC review he/she will not participate in the IEC discussion or vote on that particular project.
- The documents required for full review of the application should be complete and the relevant elements considered before a decision is made.
- Only IEC members who attend the meeting will participate in the decision.
- The decisions shall be taken in the absence of investigators, representatives of sponsors, consultants.
- The decision must be taken by majority opinion amongst the voting members of IEC after the quorum requirements are fulfilled to recommend/reject/suggest modification for a repeat review or advice appropriate steps.
- Subject expert/s may be invited to offer their views, but expert/s should not participate in the decision making process. However, his/her opinion must be recorded.
- Voting Procedure:
    - By signing the voting reference with marking Approved /Not approved/Conditional Approval suggested.
    - All the members except the Chairperson are entitled to one vote. However, in case of a tie, Chairperson will vote to break the tie.
- The secretariat shall communicate the decision in writing to the investigator within 10 days. The concurrence/Voting of the member will be recorded in the minutes as–
- Agreed: in favour
- Disagreed: Against
- CA: Conditional Approval

- After the meeting the committee may make one of the following recommendations.
- `Approved:` The study is approved in its present form
- `Approved subject to modifications:` This is a conditional approval indicating that the proposal is approved in principle, subject to the submission of certain clarifications, minor revisions, or additional documents. These will be reviewed by the member secretary, IEC on behalf of the full board. IEC, DUPMCH will empower member secretary to review the revisions/changes and grant approval if the revision/changes, clarification or additional documents are found satisfactory. The duration of time of responding back for the principal investigator shall not exceed more than 1 month.
- `Resubmit:` Extensive revisions are necessary. Principal investigator has to comply with the changes suggested by IEC and respond to the queries. The revised project will then be reviewed in the next full board meeting.
- `Deferment:` Indicating that proposal is not approved as submitted but it can be re-assessed after revisions, justifications, or additional information to address the specific reason(s) for deferment. Decision can't be arrived at present and therefore postpone to next meeting.
- `Not approved:` Indicates the study is not approved in its current form because members concerns for the protection of the participants have not been satisfactorily addressed even after the revision. A negative decision shall be supported by clearly stated reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC secretariat.
- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/benefit ratio/safety of the participants.
- In case of premature termination of study, notification shall be made indicating the reason for termination along with the summary of result conducted till date.
- The following circumstances require the matter to be brought to the attention of IEC.
- Any amendment to the protocol from the originally approved protocol with proper justification;

- Serious and unexpected adverse events and remedial steps taken to tackle them;
- Any new information that may influence the conduct of the study.
- The proceedings of the IEC meeting will be documented and the meeting minutes will be signed by the member secretary.

16. MONITORING

Site Monitoring Visit

It is the responsibility of the IEC, DUPMCH to monitor approved studies at the site. IEC, DUPMCH will perform on-site inspection of all approved ongoing studies at least once a year. Apart from the routine visits, additional visits could also be planned for the following:

- frequent protocol deviations,
- principal investigator carrying out large number of the studies at a time,
- in case of serious adverse event reported,
- non-compliance to approved protocols,
- Complaint received from Participants or any other cause as decided by IEC, DUPMCH

The selection of study for the monitoring will be discussed in the schedule IEC, DUPMCH meeting. The Chairperson will identify and designate one or more IEC members in site monitoring subcommittee or appoint an in dependent monitor to carryout monitoring of the study at site.

The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visits.

- The IEC members/Independent monitor along with IEC members will-
    - Check the log of delegation of responsibilities of study team
    - Check if the site is using latest IEC, DUPMCH approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
    - Review the informed consent document to make sure that the site is using the most recent version,
    - Observe the informed consent process or audio visual consent or audio consent, if possible.
    - Review randomly selected participants files to ensure that participants are signing the correct informed consent,
    - Observe laboratory and other facilities necessary for the study at the site, if possible. Review the project files of the study to ensure that documentation is filed appropriately.
    - Review the source documents for their completeness.
      Collect views of the study participants, if possible.
      Review the Site Master file an Investigational Products' storage and temperature
      Fill the Study (site) Monitoring Visit Report Form (Refer Annexure12)
- After the visit, member secretary will prepare a compiled report from individual monitors' site monitoring visit forms and their comments. This report shall describe the findings/observations of the monitoring visit.
- Member secretary will present the monitoring report at the next full board IEC, DUPMCH meeting and the concerned IEC member/independent monitor will provide additional details/ clarifications to members, as required.
- The IEC, DUPMCH shall discuss the findings of the monitoring process and decide appropriate specific action to be taken. Some of the actions which can be taken are as follows:
    - Continuation of the project with or without changes,
    - Restrictions on enrolment,
    - Recommendations for additional training,

- Recruiting additional members in the study team,
- Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
- Suspension of the study, etc.

- The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form
- The final decision taken at the full board IEC/the site monitoring visit report by the Chairperson is recorded in the Site Monitoring Visit Report Form
- The Secretariat will retain the copy of the report in the protocol file.
- The copy of IEC, DUPMCH subcommittee report on Site Monitoring Visit will be shared with a forwarding letter to the P.I.

Continuing Review of Study Protocols

- IEC, DUPMCH shall ensure to receive and review progress report every six month and minimum yearly after the initiation of the study for both the clinical trials, academic trials and biomedical and health research studies. All Academic research, review progress report shall be as per Annexure14.
- For clinical trials, progress reports will be discussed in a full board meeting. Based on the review and discussion in a IEC, DUPMCH meeting, the decisions will be recorded and communicated to PI in writing by the IEC, DUPMCH as 1) noted, when IEC, DUPMCH approves the project to be continued without any modifications, 2) Modification recommended, when the modifications suggested by IEC, DUPMCH needs to be amended by PI and then resubmission has to be done by the PI, 3) or the discontinuation of the project. Further, if there are any significant findings that have been observed during review process, this will be communicated to Principal Investigator.
- The final decision taken about the study will be communicated to PI within 10 days of the meeting.
- Investigator shall provide the response within 21 days to the IEC, DUPMCH.

- IEC, DUPMCH should review the SAE reports from the site as well as from other sites and should take appropriate action.

Adverse Events and Serious Adverse Event Monitoring:

All serious, unexpected and associated events shall be notified by PI to the Ethics committee as per regulatory requirement. The primary responsibility of IEC, DUPMCH is to review and address SAE and unexpected events involving risks to the research participants as per New Drugs and Clinical Trial Rules 2019.

Reporting Timeline of the SAE:

- All SAEs including Deaths should be reported by the Principal Investigator within 24 hours of their occurrence to IEC, DUPMCH, Sponsor or its representative, CDSCO (in case of studies that require approval of the CDSCO) and head of the Institute as per the format specified in New drugs and Clinical Trial rules, 2019
- Secretariat will be responsible for receiving all the documents pertaining to the adverse event.
- In case of SAE, the report with due analysis will be submitted by the Principal Investigator within 14 calendar days.
- In case of SAE, the report with due analysis will be submitted by the sponsor within 14 calendar days.
- Investigator is responsible for sending all follow up reports for all onsite SAEs till the event is resolved.
- In case the event is Death due to disease progression, the event should be notified in the SAE reporting format unless specified in the protocol.

- Upon receipt of any SAE related report, the IEC, DUPMCH secretariat will verify that the report is complete and is duly signed and dated by the Principal Investigator or the Sponsor as the case may be. If the report has been received beyond the specified time, this will be considered as a violation.
- Member secretary will sign and write the date and type of report on which the report is received and then will forward the same to subcommittee for SAE.
- For Initial SAE Reported within 24 hrs of the occurrence, an expedited review will be conducted by IEC, DUPMCH members at least within 3 working days of the receipt of the SAE report. The subcommittee may be formed to investigate the case in detail at site.
- If it seems necessary during expedited meeting, the committee can recommend immediate actions to be taken for the study at site.
- The IEC, DUPMCH secretariat will draft a formal letter to the concerned Principal Investigator and will inform him/her about the IEC, DUPMCH decision taken during the meeting or queries raised by the subcommittee during investigation within 7 days.
- After receiving due analysis report from PI within 14 calendar days and query response from PI regarding the raised queries, a full board IEC, DUPMCH meeting shall be conducted within a week.
- The SAE will be discussed at the full board meeting. The subcommittee if formed shall present their opinion on the causality assessment. The Chairperson will invite all members to voice their opinions and ensure free discussion.

The consensus decision shall be made during the meeting which requires the specific actions. Some of them are as follows:

- Direct the PI to re-evaluate the event as to whether it is AE/SAE and report to IEC.
- Request further follow up information or additional details
  Recommend an amendment to the protocol, ICD, or any other study related document

- Suspend the study for a fixed duration of time/additional information is obtained/review is completed.
  Suspend enrolment of new research participants;
- Terminate the study.
- Any other appropriate actions.

Any of the above recommendations shall be communicated to the Investigator in writing or through telephone or email, within 24 hours.

IEC, DUPMCH shall determine the causality (Relationship of the SAE with the study drug) with the expertise, experience and skill reviewer if required.
In case of serious adverse event or death occurring to the clinical trial subject, &/or Biomedical and Health Research the IEC, DUPMCH shall forward its due analysis decision for quantum of compensation determined as per the formula specified in the, New drugs and Clinical Trial rules, 2019 to be paid by the sponsor or its representative and shall pass orders as deemed necessary within ninety days of the receipt of the report of the serious adverse event.

IEC, DUPMCH shall calculate the compensation to be paid to the subject based on New Drugs and Clinical Trial Rules 2019. (Refer Annexure 13)

All off site SAEs shall be notified by PI to IEC, DUPMCH. Offsite SAEs if required may be discussed in IEC, DUPMCH meeting and will be filed in respective project file.

- Onsite AE:

  All the onsite adverse events shall be recorded by PI and shall be notified to IEC, DUPMCH.

  Member secretary shall be responsible for reviewing adverse event notification. If required Member secretary may inform Investigator to present the adverse event reported to the members of the IEC, DUPMCH in a scheduled full board meeting.

The reported adverse event shall be discussed in a meeting and the deliberations shall be recorded in detail in minutes of that meeting.

Appropriate actions shall be taken by IEC, DUPMCH depending on the severity and nature of the adverse event and relatedness of the event with the study drug.

IEC, DUPMCH may also send the letter to PI for justification or clarification or further information on any AE reported.

Protocol Deviations/Violations:

IEC, DUPMCH is responsible for receiving non-compliance reports and taking appropriate actions after thorough review and discussion.

Protocol violation: A divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Examples of protocol violations may include the following:

- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events
- Improper breaking of the blind
- Use of prohibited medication
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel
- Incorrect or missing tests
- Mishandled samples

`Protocol Deviations:` Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data.

- Deviations may result from the action of the subject, researcher, or research staff. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non- compliance with the research protocol on the part of a researcher.

Examples of a deviation include:

- A re-scheduled study visit
- Failure to collect an ancillary self-reported questionnaire
- Subject's refusal to complete scheduled research activities

The Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC, DUPMCH. The IEC, DUPMCH members performing monitoring of the project at trial site may also report any protocol deviation/violation/noncompliance observed. The Secretariat can detect a protocol deviation/non- compliance/violation from failure to comply with statutory requirement/failure to respond to requests from IEC, DUPMCH within reasonable time limit. The members of the IEC, DUPMCH may also detect protocol deviation/violation while scrutinizing study progress report. The Protocol deviation/violation reports may also be received from research participant or independent person or from Head of the Institution.

- Each allegation is taken seriously and reviewed in a consistent, prompt, and professional manner. Additionally, care is taken to maintain confidentiality.
- The Chairperson/IEC members will review the information available and take a decision depending on the seriousness of the violation.

- The decision will be taken to ensure that the safety and rights of the research participants are safe guarded.
- The decision will be taken by consensus and if no consensus is arrived at, voting will be conducted.

The actions taken by the IEC could include one or more of the following:

1. Determine that no further action is required, or take other actions as appropriate.
2. Suggest modifications to the protocol
3. Require additional training of the investigator and study team.
4. Reprimand the PI.
5. Observe the research or consent process.
6. Enlist measures that the PI would undertake to ensure that such deviations/noncompliance / Violations do not occur in future.
7. Suspension or termination of the study, etc.

- The decision will be communicated to the PI within 14 days except if the decision is project suspension/termination, which will be communicated to the Principal Investigator within 1 working day of the meeting.
- The Secretariat will record the decision reached on the protocol deviation / violation in the minutes of the meeting.

17. SUB-COMMITTEE(S) OF IEC, DUPMCH

* For Review of SAE / AE/ SOP preparation/any other activity, subcommittee would be formed by the chairman as per requirement: A sub-committee would examine all amendments, adverse events and serious adverse events reported / submitted to the IEC, DUPMCH and present them to the full IEC, DUPMCH for comments and approvals. The investigators would not be required to be present while these are discussed at the IEC meeting.

Compensation: New sub-committees may be constituted as and when required for such purpose. A sub-committee would examine seriousness criteria and performs causality assessment for Serious Adverse Events and based on that calculates subject compensation as per New drugs and CT rules 2019. Protocol Amendment/Revision: A sub-committee would be formed as and when there is a requirement of amendment/Revision of the EC SOP.

18. PRINCIPAL INVESTIGATOR'S RESPONSIBILITY

Principle investigator shall be overall responsible for keeping the IEC informed about every aspect of the ongoing study.

- A Principal Investigator shall not be concurrently running more than three clinical trials.
- PI shall notify IEC, DUPMCH about the Site initiation visit and First Patient Randomization.
- All SAEs and the interventions undertaken would be intimated and recorded as document filled in the ADR form along with causality assessment.
- Protocol deviation, if any, would be informed with adequate justifications.
- Any amendment to the protocol would be resubmitted for renewed approval.
- Any new information related to the study would be communicated.
- Premature termination of study would be notified with reasons along with summary of the data obtained so far.
- Change of investigators / sites would be informed.
- Inform IEC about study completion or discontinuation with reasons.
- Justification for approval to restart studies discontinued earlier.
- The PI must register the Clinical trial with CTRI within 2 weeks of IEC approval letter and inform the IEC of the CTRI registration number before starting trial.
- Progress reports (Refer Annexure 14) are to be submitted six monthly in case of Academic trials.

- In case of clinical trials, PI shall sent the study progress report to IEC, DUPMCH which must include overall recruitment status of the site, any AE or SAE reported, any revisions/amendments in approved protocols, protocol deviations/violations if any reported, etc.
- Final clinical study report should be submitted by PI at the end of study.

FOLLOW UP PROCEDURES:

In case of all Biomedical and Health Research, six month progress report shall be submitted by the PI to IEC, DUPMCH in prescribed format as given in Annexure 14.

- In case of clinical trials, PI shall sent the study progress report to IEC, DUPMCH which must include overall recruitment status of the site, any AE or SAE reported, any revisions/amendments in approved protocols, protocol deviations/violations if any reported, etc. This shall be reviewed in the forthcoming full board IEC, DUPMCH meeting. If deemed necessary by the member secretary, the Investigator may be informed to present the study progress report in a scheduled IEC, DUPMCH meeting.
- The detailed discussion of this progress report amongst the IEC, DUPMCH members shall be captured in the minutes of the meeting.
- All clinical trial approvals are of one year duration. If recruitment of the trial is of longer than one year, or if follow up of the patient is for longer duration, PI will have to take annual renewal from IEC, DUPMCH. The PI has to submit annual report and fees as per IEC, DUPMCH norms. PI will represent the report in forthcoming IEC, DUPMCH meeting and to get renewal for the study one more year.
- For all Biomedical and Health Research upon completion, PI will request IEC, DUPMCH to issue the approval letter. IEC, DUPMCH upon checking the abstract, progress report, plagiarism report (in case of Dissertation study), and master chart of data gathered, will issue a completion certificate to PI.
- For all clinical trials, PI will notify to the IEC, DUPMCH about the study completion status of the site and the final Clinical Study Report (CSR).

19. RECORD KEEPING AND ARCHIVING

- CV of all members of IEC, and Confidentiality agreement, minutes of all meetings duly signed by the Chairperson/ and Member Secretary, Copy of all correspondence with members, researchers and other regulatory bodies and all study related documents (study protocols with enclosed documents, progress reports, and SAEs) shall be archived for minimum of 5 years after the completion of study.
- If facilities are available, the IEC, DUPMCH will make a soft copy of the documents and store in the archive office of IEC, DUPMCH. All documents related to the study file will be gathered, classified and combined together appropriately.
- All active files will be kept in a secured file cabinet with controlled access. Only authorized individuals i.e. Secretary/Chairperson, or person authorized by them will have access to the files.
- All closed study files shall be separately archived.
- The completed/closed project files will be stored in archive boxes that are clearly labelled with the project number and title, name of PI and disposal date. The archive boxes will be sent to a secure, dry location. The access to the files should be restricted to the IEC and the regulatory authorities. The details of the archiving location should be recorded in a location register stored in the IEC office. This register should record the project number and title, name of PI and the disposal date.

Retrieving Documents

The request for retrieval shall only be made by an IEC, DUPMCH member, auditor or other authorized person by writing an application stating the purpose and signing & dating the application letter.

A member of IEC Secretariat will retrieve archived document(s) and will return the remaining file back to its place.

The Secretariat maintains a register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC Chairperson, Date and time of retrieval, Name and signature of IEC staff / Secretariat retrieving the file, Date and time of returning the file

The Secretariat will also record, sign and date when the document has been returned and kept.

Disposal of Files

The study file will be maintained in the IEC office for a period of five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off. However, all the copies of the research projects and documents submitted for IEC review shall be shredded by the authorized IEC personnel after the IEC meeting without any notification to the PI. A logbook of disposed documents will be maintained.

ANNEXURES

ANNEXURE 1: RESEARCH PROPSAL SUMMARY SHEET

(To be filled by Principal Investigator)

Title of the Project	**:**	_____
Name of Principal Investigator	**:**	_____
Designation	**:**	_____
Department	**:**	_____
Institute	**:**	_____
Email ID	**:**	_____
Contact No.	**:**	_____
Name of Co-Investigator(s)/Guide)	**:**	_____
Designation	**:**	_____
Department	**:**	_____
Institute	**:**	_____
Email ID	**:**	_____
Contact No.	**:**	_____
Proposed Budget in Rs.	**:**	_____
Project Submission Date	**:**	_____
Funded By	**:**	Self ☐ External ☐ DUPMCH ☐
Type of Study Design	**:**	☐ Observational ☐ Cross Sectional ☐ Interventional ☐ Case Control ☐ Laboratory ☐ Cohort ☐ Animal ☐ Comparative ☐ Retrospective ☐ Randomized ☐ Comparative

Duration of the Projects (in Months) :_____

Any Change after IEC DUPMCH Approval : _____

Specify Changes : _____

Submission Date : _____

HRRP Remarks : _____

Checklist for Research Proposal Submission

SR.NO	CONTENTS	YES/NO/NA
1	Covering letter of submission signed by investigators and forwarded by HOD/off. In charge	
2	Title or cover page	
3	Introduction	
4	Aim and objectives	
5	Review of literature	
6	Materials and methods	
	A. Study design	
	I. Place of study	
	II. Source of data	
	III. Related approvals	
	IV. Sample description	
	V. Selection criteria	
	1. Inclusion criteria	
	2. Inclusion criteria	
	B. Material/equipment for the study	
	C. Methodology	
	D. Informed consent form (in arati &English)	
	E. Participant information sheet (In arati & English)	
7	Statistical method	
8	Ethical issue	
9	Feasibility issue	
10	Likely outcome/benefit of study	
11	Conflict of interest	
12	Sponsors of the study, if any	
13	Sources of fund, if any	
14	Expenditure statement	
15	References (Superscript and Vancouver style)	
16	Signature of principal investigator/PG Guide	

Principal Investigator **Guide**

ANNEXURE 2: FORMULATION OF NEW SOP/REVISION OF SOP

SOP No.		
Title		
Need/Reason to Formulate New/Revision of the SOP		
Identified by :		Date:
Discussed in IEC meeting held on :		
SOP Revision Required	Yes ☐	No ☐
New SOP to be formulated	Yes ☐	No ☐
If yes, to be carried out by whom?		
If no, Why?		
Date of SOP revised		
Date SOP approved		
SOP effective date:		

ANNEXURE 3: DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITALINSTITUTIONAL ETHICS COMMITTEE
MEMBERSHIP LIST w.e.f.29th Sept, 2021.

Sr. No.	Name	Qualification with Specialization	Current Organization	Telephone number, fax number, e-mail I . D . and mailing address	Designation/ Role of member in Ethics Committee	Affiliation of member with institute that has constituted the Ethics Committee
1	Dr. Parag Ramchandra Patil	PHD Neuropharmacology	KYDSCT's college of Pharmacy	9890864219 drparagpatil@gmail.com KYDSCT'S college of Pharmacy, Sakegaon , Taluka Bhusawal, District, Jalgaon, 425201	Chairman	No
2	Dr. Rahul Prakash Bhavasar	MD Pharmacology	Dr. Ulhas Patil Medical College And Hospital	9619419807 rahulprakashbhavasar@gmail.com Department of Pharmacology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Member Secretary	Yes
3	Dr. Vaishali Baburao Nagose	MD Pathology	Dr. Ulhas Patil Medical College And Hospital	8500571871 vaishali.nagose@gmail.com Department of Pathology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Basic Medical Scientist	Yes
4	Dr. Shubhangi Devendra Chaudhari	DNB OBGY	Dr. Ulhas Patil Medical College And Hospital	9765972347 shubhangi121277@gmail.com Department of Obstetrics & Gynaecology, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Clinician	Yes
5	Adv. Satish Govindrao Gadge	LLM	Private Practice	7387193453 satishgadge60@gmail.com C/O P-51, MIDC, Girl's hostel quarters, Godavari college of engineering, Jalgaon Bhusawal road, 425003	Legal Expert	No
6	Dr. Prashant Sudhakar Warke.	MBA	Godavari Institute of Management and Research	9325150006 warke.prashant01@gmail.com Godavari Institute of Management and Research, Plot no P-54, near Bhart Petroleum, Addl MIDC, Bhusawal road Jalgaon 425003	Social Scientist	No
7	Mrs. Swara Jayesh Waghodkar	B. Com	House wife	7350043418 jwaghodkar@gmail.com Nagosen colony Kandhari, Bhusawal, Jalgaon 425201	Lay Person	No

8	Dr. Nilesh Prakash Bendale	MD Community Medicine	Dr. Ulhas Patil Medical College And Hospital	9604692540 nileshbendale@rediffmail.com Department of Community Medicine, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Basic Medical Scientist	Yes
9	Dr. Shivaji Pandurangrao Sadulwad	MS General Surgery	Dr. Ulhas Patil Medical College And Hospital	9881604567 dr.shivajisadulwad72@gmail.com Department of Surgery, Dr. Ulhas Patil Medical College and Hospital, Jalgaon khurd 425309	Clinician	Yes
10	Mr. Girish Ashok Kulkarni.	PHD Electrical Engineering	HSM's Shri Sant Gadge Baba College of Engineering and Techniology, Bhusawal,	9767393498 girish227252@gmail.com Shikshak colony, shanti nagar, behind dnyneshwar garden, near hanuman mandir, Bhusawal, 425201, Jalgaon, Maharashtra.	Philosopher	No

ANNEXURE 4: CONFIDENTIALITY AGREEMENT FORM FOR INDEPENDENT CONSULTANTS

I,_____ (Name and Designation) as a non-member of IEC understands that the copy/copies given to me by the IEC is (are) confidential. I shall use the information only for the indicated purpose as described to the IEC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IEC.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

_____ _____

Undersigned Signature Date

_____ _____

Chairperson of IEC Date

I, _____ (Enter Name) acknowledge that I have received a copy of this Agreement signed by Chairperson, IEC and me.

_____ _____

Signature of the recipient Date

ANNEXURE 5: ONE PAGE CV FORMAT FOR IEC, DUPMCH MEMBERS/INVESTIGATORS

Curriculum Vitae

Full Name	:	
Date of Birth	:	
Designation	:	
Language Proficiency	:	
Professional Mailing Address	:	
Contact No.	:	+91
Email ID	:	

Academic Qualifications		
Degree/Certification	**Date (YYYY)**	**Institution, Country**
Medical Registration Number		

Current and Previous Relevant Positions Including Academic Appointments		
Start and End Date	**Title**	**Institution or Company, State/Province/Country**

ICH – GCP Training : Yes / No, if Yes then specify month & year
NDCT RULES 2019
Research Experience

Signature: **Date:**

ANNEXURE 6: CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT FORM

In recognition of the fact, that I,…… here in referred to as the "Undersigned", have been appointed as a member of the Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital and would be asked to assess research studies involving human participants in order to ensure that they are conducted in a humane, scientific and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines; Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities with respect to the protection of the rights and well-being of human participants; The undersigned, as a member of the IEC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that my performance of this agreement is consistent with DUPMCH policies and any contractual obligations it may have to third parties.

Undersigned Signature Date

Conflict of Interest

It has been recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human participants.

In accordance of the policy of the IEC, I shall not participate in the review, comment or approval of any activity in which I have a conflict of interest, except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

The Undersigned will immediately disclose to the Chairperson of the IEC all conflicts of interest for themselves and their spouses/domestic partners and dependent children.

Agreement on Confidentiality and Conflict of Interest

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the access to it, as per the right to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the IEC's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee e member.

Whenever I have a conflict of interest, I shall immediately inform the committee and recuse myself from discussion and /or voting on the issue and leave the room while the discussion is ongoing"

Whenever I have a conflict of interest, I shall immediately inform the committee all conflicts of interest for myself and my spouses/domestic partners and dependent children.

Name of the spouses/domestic partners (if applicable) :_____

Name of the dependent children (if applicable) :_____

I, Dr. ……. have read and I accept the aforementioned terms and conditions as explained in this Agreement.

_____

Undersigned Signature Date

_____

Chairperson, DUPMCH

Date:-

ANNEXURE 7: VOTING REFERENCE

Protocol Title:
Protocol Number:
Principal Investigator:
Reviewed in EC meeting dated:

Sr. No	Member Name	Role in EC	Approved	Sign & Date
1			Y/N/CA*	
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

(*CA – Conditional Approval)

The committee empowers the member secretary to grant permission, if PI compiles to the raised query within 30 days.

ANNEXURE 8: STANDARD OPERATIVE PROCEDURE (SOP) FOR SPECIAL/VULNERABLE POPULATIONS

Studies in special populations:

Vulnerable populations are those that are relatively(or absolutely)incapable of protecting their own interest, either due to insufficient power, intelligence, education, resources, strength, or other needed attributes. Hence, they lack the capacity to provide informed consent or their willingness to participate in research and may be unduly influenced.
The special/vulnerable populations include pregnant women, fetuses and neonates, children, prisoners, students, employees of the sponsor or investigator and economically or educationally disadvantaged persons.
The investigator is required to indicate the involvement of potentially vulnerable populations/group to the IEC, DUPMCH in the application documents (usually in the protocol) and provide description of the safeguards to protect the rights and welfare of the vulnerable participants.

1. Research involving pregnant women, fetuses and neonates.

The IEC, DUPMCH may approve the research involving these participant populations if they satisfy the following conditions.

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals and clinical studies, including the studies on non-pregnant women have been conducted for assessing potential risks to the pregnant women and fetuses.
- A risk to the fetus is caused solely by the inventions or procedures which are of the direct benefit for the woman or the fetus.
- Where the risk to the fetus is not greater than minimal and the purpose of the research is the development of the biomedical knowledge which cannot be obtained by any other means.
- When there is a least possible risk for achieving the objectives of the research.
- When the research holds out the prospect of the direct benefit to the pregnant woman

Research involving the neonates:

A. After delivery: The neonates may be involved in the research if all of the following conditions are met with.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted for
   assessing the potential risks to the neonates.
2. The individual(s) providing consent under the applicable regulations is/are fully informed about the reasonably foreseeable impact of research on the neonate.
3. The regulatory requirements should be met as applicable.

B. Neonates of uncertain viability: After delivery, until it is ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by federal regulations unless the following conditions are also met with:

1. That the research holds the prospect of enhancing the probability of survival of the neonate, and any risk if expected should be the least for achieving the objectives.
2. Purpose of the research is development of the knowledge which cannot be obtained by other means and there will be no risk to the neonates that result from the research.
3. The legally effective informed consent of either parent of the neonate or, if neither of the parent is able to give the consent because of the unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative has to be obtained in accord with.

C. Nonviable neonates: After delivery, a nonviable neonate may not be involved in research covered by federal regulations unless the following conditions are met with.

1. Vital functions of the neonate will not be artificially maintained.
2. Research will not terminate the heart beat or respiration of the neonate.
3. There will occur no risk to the neonate from the research.
4. The purpose of research in the development of knowledge cannot be obtained by other means.
5. A legally effective informed consent of both the parent of the neonate should be obtained in accord with. However, if one of the parents is unable to consent because of unavailability, incompetence or temporary incapacity, the informed consent of the other parent will suffice to meet the requirements.

Research involving after delivery: The placenta, the fetus, fetal material, tissue or organs excised from a dead fetus. Such research shall be conducted only in accordance with the applicable federal, state, or local laws regarding such activities

Research involving pregnant woman:

Research involving the pregnant woman is not allowed until and unless

- The research includes adequate provisions to monitor the risks to the participant and to the fetus
- The potential participant is selected with adequate considerations.
- Adequate provision is made to monitor actual consent
- The research is continually evaluated to determine if any unanticipated risk have arisen.

2. Research involving the prisoners:

Prisoner include any individual who is confined or detained in a penal institution or sentenced to serve time in a penal institution under criminal or civil statute, or detained in other facilities by virtue of statutes or commitment procedure which provide alternatives to criminal prosecution or incarceration in a penal institution, or detained pending arraignment, trial or sentencing. Regulations do not differentiate between detention, jail or prison.

However, IEC, DUPMCH requires that if the enrolment for research in such population has to be held then the following conditions are to be met with:

- The study causes, effects and processes of incarceration no more than minimal risk and no more inconvenience to the participants.
- The study should present no more than minimal risk and no more than inconvenience to the participants.
- The research under review involves solely research practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the participant.
- In cases where prisoners may not be benefitted from the research because they are assigned to a control group in consistence with the protocol approved then the study may proceed on federal approval.

- The risk involved in the research is commensurate with risks that would be accepted by non-prison volunteers.
- Unless the investigator provides justification in writing for following, some other procedures, control participants must be selected randomly from the group of eligible prisoners for the research project.

When an enrolled participant becomes a prisoner during a research:

- For the ongoing research projects, if an enrolled participant becomes a prisoner and the study not being reviewed and approved by the IEC, DUPMCH for the inclusion of prisoners , the investigator is responsible for notifying the IEC, DUPMCH as soon as possible and request determination from chair that in the best interest of the incarcerated prisoner participant to continue certain study interventions as a non-participant for patient safety reasons until such time he/she can be withdrawn from the study, otherwise the investigator will withdraw the now prisoner participant from the study as follows:
- If a participant becomes a prisoner after enrolment in research, the investigator must cease all the research interactions and interventions with the participant.
- The investigator shall report this situation to the IEC, DUPMCH in writing
- In special circumstances in which the principle investigator asserts that it is in best interests of the participant to remain in the research while incarcerated, the IEC, DUPMCH may determine the same and the participant may continue until the requirements are satisfied.
- At the earliest opportunity on receiving the investigator's notice or otherwise becoming aware of the incarceration of a participant, the IEC, DUPMCH shall review the protocol again with a prisoner representative as a member of IEC, DUPMCH. Based upon this review the involvement of the prisoner participant may be either approved or withdrawn.

3. **Research involving children:** Approval of the research in children is based on the probable risks, associated discomforts and possible benefits.

3.1 Determination of probable risks and associated discomforts:

The assessment of the probability and magnitude of the risk may be different for the sick children and may vary depending on the diseases or the conditions the participant may have. However, the IEC, DUPMCH shall consider that children suffering from chronic illnesses who are accustomed to invasive procedures are placed at minimal risk. The IEC, DUPMCH shall also consider the extent to which research procedures would burden any child, regardless of whether the child is accustomed to the proposed procedure. Depending on the degree of risk benefit to individual participants can be as follows

- Research not involving greater than minimal risk.
- Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual participants.
- Research involving greater than minimal risk with no prospect of direct benefits to individual participants, but likely to yield generalizable knowledge about the participants disorder or condition.
- Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate serious problem affecting the health or welfare of children.

3.2 Determination of possible benefits:

To assess the possible benefits of research in children, the IEC, DUPMCH shall consider the variability in the health statuses among the participants.

3.3 Wards of the state:

When the research involves greater than minimal risk to the participants with no prospect of direct benefit, the research must either be related to their status as wards, or be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards. Then, the IEC, DUPMCH shall require for each child who is a ward, appointment of an advocate in addition to any other individual acting on behalf of the child as a guardian.

3.4 HIV- infected children:

The IEC, DUPMCH shall give special attention to groups of children such as these, who need special protections, should not be denied the opportunity to participate in research that may potentially benefit them.

3.5 Institutionalized children:

The IEC, DUPMCH shall not allow the Institutionalized children to be included as participants simply because of their availability to the investigator.

3.6 Parental permission:

Children may be participants of research only if the Informed Consent from the parent or the legal guardian is obtained (**Refer Annexure 18)**. The IEC, DUPMCH shall determine whether the permission of both the parents is necessary, and the conditions under which one parent may be considered is not reasonably available.

3.7 Assent of children:

The IEC, DUPMCH shall determine whether adequate provisions are made for soliciting the assent of the children. The assent shall be obtained from the participating child in the format prescribed by IEC, DUPMCH.

3.8 Considerations for assent (as per guidelines of New Drugs and CT Rules 2019)

- There is no need to document assent for children below 7 years of age.
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
- Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the EC.
  (Refer Annexure 19).

4. Research involving Geriatrics:

Geriatric population is considered for research if the disease intended to be treated is characteristically a disease of aging; or the population to be treated is known to include substantial numbers of geriatric patients; or when there is specific reason to expect that conditions common in the elderly are likely to be encountered; or When the new drug is likely to alter the geriatric patient's response (with regard to safety or efficacy) compared with that of the non-geriatric patient.

5. Other groups and research situations requiring special consideration:

Every project reviewed by the IEC, DUPMCH is evaluated for circumstances that may place participants in vulnerable situations and call for special protection. When a participant group is identified as being vulnerable in a particular research setting, the IEC, DUPMCH will consider whether the protocol provides adequate pretentions for those participants. The IEC, DUPMCH may require additional protections for safeguarding those participants as condition of approval. Some of such situations are described below.

Other special populations may include cognitively impaired participants, traumatized and comatose patients, terminally ill patients, students, normal volunteers, minorities, and participants in AIDS research, employees of the sponsor or investigator, and the elderly. The IEC, DUPMCH shall determine special protections necessary for these groups on a case by case basis, taking into account the risks and benefits.

5.1 Cognitively impaired participants:

The cognitively impaired participants are defined as having a psychiatric disorder (e.g. psychosis, neurosis, and personality or behavior disorders), an organic impairment (e.g. dementia) or a developmental disorder (e.g. mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is diminished.

5.1.1 Others include persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may be compromised in their ability to make decisions in their best interest. The IEC, DUPMCH shall determine the degree of risk of a research protocol involving cognitively impaired participants, a minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care.

5.1.2 However, for the research that does not involve beneficial interventions and that presents more than minimal risk, the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the participant's condition.

5.1.3 Studies involving the participants who are cognitively impaired may take place over extended periods. The IEC, DUPMCH shall consider whether periodic re-consenting of individuals is required to determine that a participant's continued involvement is voluntary. The IEC, DUPMCH may require that the investigators re-consent participants after taking into account the study's anticipated length and the condition of the individuals to be included.

5.2 Informed consent: Cognitive impairment alone should not disqualify a person from consenting to participate in research and making an informed voluntary choice; rather the investigator shall present specific evidence of cognitive impairment.

6. Research in schools:

When research will be conducted in schools, the IEC, DUPMCH will consider, whether protection required by the law that apply to research in schools, is adequately met with.

7. Students, employees and others in subordinate positions:

Students, employees and other persons in subordinate positions or positions of lesser power or status provides a pool of easily accessible research participants. The IEC, DUPMCH will consider whether the autonomy and confidentiality of these individuals are adequately protected, which may include the following;

- That incentives for participation do not present undue influence
- That participants have the ability to decline participation
- That confidentiality is maintained for self-disclosures of a personal nature
- For students, if course credit is given for participation, that alternatives are no more burdensome than the participation in research are available for receiving equal credit.

8. Economically or educationally disadvantaged persons and other groups requiring special consideration:

The economically or educationally or educationally disadvantaged, homeless persons, the elderly and the members of particular minor group are only some of the additional populations that may require special protection in the research environment. When such groups are specifically targeted as research participants, the IEC, DUPMCH will consider whether adequate safeguards are in place to protect such participant groups from risks unique to the population and that researchers do not use their position to unduly influence participation.

ANNEXURE 9: IEC, DUPMCH REVIEW CHECKLIST

Name of IEC member/Independent Consultant**:**
Protocol Reviewed:

Principal Investigator**:**

Sr. No	**Topics of Review**	**Adequate/Relevant (Mark √ or ×)**	**Inadequate? Irrelevant (Please specify inadequacy**
1	Covering letter bearing		
	a. Title of the study		
	b. Name and Sign of PI		
	c. Name of the guide		
	d. UG/PG/Clinical Research		
	e. Type of study, PhD, Research Project (Student/Faculty)		
2	Introduction		
3	Aim (s) & Objective (s)/ Rationale of the study		
4	Information Brochure/Review of Literature		
5	Protocol Design		
6	Statistical Methods		
7	Ethical Issues		
8	Feasibility Issue		
9	Likely Outcome/Benefit of the study		
10	References-		
	a. Cited Properly		
	b. Vancouver style		

Sr. No	Topics of Review	Adequate/Relevant (Mark √ or ×)	Inadequate? Irrelevant (Please specify inadequacy
11	Participant/Patient Information Sheet		
	a. English		
	b. Vernacular Language (arati		
	c. Vernacular Language (Hindi)		
12	a. Informed Consent Form English		
	b. Vernacular Language (arati)		
	c. Vernacular Language (Hindi)		
13	Case Report Form / Proforma/Questionnaire		
14	Financial Considerations and Clinical Trial Agreement (CTA),if Applicable		
15	Signature of Guide and Student		
16	Overall Comments		
17	Signature of IEC Member		

ANNEXURE 10: CONTENTS OF THE PROPOSED PROTOCOL FOR CONDUCTING

CLINICAL TRIALS

Title Page

(a) Full title of the clinical study,

(b) Protocol, Study number, and protocol version number with date.

(c) The Investigational New Drug (IND) name/number of the investigational drug.

(d) Complete name and address of the Sponsor and contract research organization if any.

(e) List of the investigators who are conducting the study, their respective institutional affiliations and site locations

(f) Name of clinical laboratories and other departments and/or facilities participating in the study.

Table of Contents

1. **Background and introduction:**

(a) Preclinical experience

(b) Clinical experience

Previous clinical work with the new drug should be reviewed here and a description of how the current protocol extends existing data should be provided. If this is an entirely new indication, how this drug was considered for this should be discussed. Relevant information regarding pharmacological, toxicological and other biological properties of the drug/biologic/medical device, and previous efficacy and safety experience should be described.

2. **Study rationale:** This section should describe a brief summary of the background information relevant to the study design and protocol methodology. The reasons for performing this study in the particular population included by the protocol should be provided.

3. **Study objective:** (primary as well as secondary) and their logical relation to the study design.

4. **Study design:**

a) Overview of the study design: Including a description of the type of study (i.e., double-blind, multicentre, placebo controlled, etc.), a detail of the specific

treatment groups and number of study Subjects in each group and investigative site, Subject number assignment, and the type, sequence and duration of study periods.

b) Flow chart of the study

c) A brief description of the methods and procedures to be used during the study.

d) Discussion of study design: This discussion details the rationale for the design chosen for this study.

5. **Study population:** The number of subjects required to be enrolled in the study at the investigative site and by all sites along with a brief description of the nature of the subject population required is also mentioned.

6. **Subject eligibility:**
   a. Inclusion criteria
   b. Exclusion criteria

7. **Study assessments**: plan, procedures and methods to be described in detail.

8. **Study conduct** stating the types of study activities that would be included in this section would be: medical history, type of physical examination, blood or urine testing, electrocardiogram (ECG), diagnostic testing such as pulmonary function tests, symptom measurement, dispensation and retrieval of medication, Subject cohort assignment, adverse event review, etc.
   Each visit should be described separately as Visit 1, Visit 2, etc.

Discontinued subjects: Describes the circumstances for Subject withdrawal, dropouts, or other reasons for discontinuation of Subjects. State how drop outs would be managed and if they would be replaced describe the method of handling of protocol waivers, if any. The person who approves all such waivers should be identified and the criteria used for specific waivers should be provided.
Describes how protocol violations will be treated, including conditions where the study will be terminated for noncompliance with the protocol.

9. **Study treatment-**

a) Dosing schedule (dose, frequency, and duration of the experimental treatment) Describe the administration of placebos and/or dummy medications if they are part of the treatment plan. If applicable, concomitant drug(s), their doses, frequency, and duration of concomitant treatment should be stated.
b) Study drug supplies and administration: A statement about who is going to provide the study medication and that the investigational drug formulation has been manufactured following all regulations Details of the product stability, storage requirements and dispensing requirements should be provided.
c) Dose modification for study drug toxicity: Rules for changing the dose or stopping the study drug should be provided.
d) Possible drug interactions.
e) Concomitant therapy: The drugs that are permitted during the study and the conditions under which they may be used are detailed here. Describe the drugs that a Subject is not allowed to use during parts of or the entire study. If any washout periods for prohibited medications are needed prior to enrolment, these should be described here.
f) Blinding procedures: A detailed description of the blinding procedure if the study employs a blind on the Investigator and/or the Subject.
g) Un-blinding procedures: If the study is blinded, the circumstances in which un-blinding may be done and the mechanism to be used for un-blinding should be given.

10. Adverse Events:

Description of expected adverse events should be given. Procedures used to evaluate an adverse event should be described.

11. Ethical considerations: Give the summary of:

a) Risk/benefit assessment:
b) Ethics committee review and communications
c) Informed consent process
d) Statement of subject confidentiality including ownership of data and coding procedures.

12. Study monitoring and supervision:

A description of study monitoring policies and procedures should be provided along with the proposed frequency of site monitoring visits, and who is expected to perform monitoring.

Case Record Form (CRF) completion requirements, including who gets which copies of the forms and any specific required in filling out the forms Case Record Form correction requirements, including who is authorized to make corrections on the Case Record Form and how queries about study data are handled and how errors, if any, are to be corrected should be stated.

Investigator study files, including what needs to be stored following study completion should be described.

13. Investigational Product Management:

a) Give investigational product description and packaging (stating all ingredients and the formulation of the investigational drug and any placebos used in the study).
b) The precise dosing required during the study.
c) Method of packaging, labeling, and blinding of study substances.
d) Method of assigning treatments to subjects and the subject identification code numbering System.
e) Storage conditions for study substances.
f) Investigational product accountability: Describe instructions for the receipt, storage, dispensation, and return of the investigational products to ensure a complete accounting of all investigational products received, dispensed, and returned or destroyed.
g) Describe policy and procedure for handling unused investigational products.

14. Data Analysis:

Provide details of the statistical approach to be followed including sample size, how the sample size was determined, including assumptions made in making this determination, efficacy endpoints (Primary as well as Secondary) and safety endpoints

Statistical analysis: Give complete details of how the results will be analyzed and reported along with the description of statistical tests to be used to analyze the primary and secondary endpoints defined above. Describe the level of significance, statistical tests to be used, and the methods used for missing data; method of evaluation of the data for treatment failures, non-compliance, and Subject withdrawals; rationale and conditions for any interim analysis if planned.

Describe statistical considerations for Pharmacokinetic (PK) analysis, if applicable.

15. Undertaking by the Investigator:

1. Full name, Address and title of the Principal Investigator (or Investigators when there is no Principal Investigator)
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who willbe assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:
    i. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
    ii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favorable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
    iii. I agree to personally conduct or supervise the clinical trial at my site.
    iv. I agree to inform all trial subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
    v. I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.
    vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
    vii. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and

they have been informed about their obligations in meeting their commitments in the trial.

viii. I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

ix. I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

x. I agree to inform all serious adverse events to the Central Licensing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event

xi. The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

xii. I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

xiii. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with date.

16. Appendices:

Provide a study synopsis, copies of the informed consent documents (patient information sheet, informed consent form etc.); Case Record Form (CRF) and other data collection forms; a summary of relevant pre- clinical safety information and any other documents referenced in the clinical protocol.

ANNEXURE 11: ELEMENTS OF THE INFORMED CONSENT

1. **Checklist of informed consent documents for clinical trial subject Essential elements:**

   i. Statement that the study involves research and explanation of the purpose of the research.
   ii. Expected duration of the participation of subject.
   iii. Description of the procedures to be followed, including all invasive procedures.
   iv. Description of any reasonably foreseeable risks or discomforts to the Subject.
   v. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
   vi. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
   vii. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.
   viii. Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).
   ix. Statement describing the financial compensation and the medical management as under:
      (a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
      (b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.
   x. An explanation about who to contact for trial related queries, rights of Subjects and in the event of any injury.
   xi. The anticipated prorated payment, if any, to the subject for participating in the trial.

   xii. Responsibilities of subject on participation in the trial.

xiii. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

xiv. Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

xv. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

xvi. Any other pertinent information.

Additional elements, which may be required:

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b) Additional costs to the subject that may result from participation in the study.

(c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

(e) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of Subjects enrolled in the study.

2. Format of informed consent form for Subjects participating in a clinical trial

Informed Consent form to participate in a Clinical Trial Study Title:

Study title	:	
Study Number:	:	
Subject's Initials	:	
Date of Birth/Age	:	
Subject's Name	:	
Address of the Subject	:	
Qualification	:	
Occupation	:	Student or Self-Employed or Service or Housewife or Others (Please click as Appropriate)
Annual Income of the subject	:	

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

			Please initial box (Subject)
I.	I confirm that I have read and understood the information sheet dated……..for the above study and have had the opportunity to ask questions.	:	
II.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	:	
III.	I understand that the Sponsor of the clinical trial, others working on the Sponsor behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	:	
IV.	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	:	
V.	I agree to take part in the above study.	:	

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

_____

Date:____/____/_____

Signatory's Name:_____

Signature of the Investigator:_____

Date:____/____/_____

Study Investigator's Name:_____

Signature of the Witness:_____

Date:____/____/_____

Name of the Witness:_____

Copy of the Patient information Sheet and duly filled Informed consent form shall be handed over to the Subject his or her attendant.

ANNEXURE 12: STUDY MONITORING VISIT REPORT FORM

Protocol Number and Title	**:**	
Principle Investigator	**:**	
Institute/Department	**:**	
Type of Study	**:**	☐ Investigator Initiated ☐ Pharma ☐ Thesis
IEC, DUPMCH Approval Date	**:**	
Site Initiation Date	**:**	
Study Status	**:**	☐ Ongoing ☐ Completed ☐ Follow-up ☐ Suspended ☐ Terminated ☐ Closed ☐ Closed Prematurely
If the study is Suspended/Terminated/Closed Prematurely, Kindly provide reason:_____		
Subject Recruitment Status	**:**	
Total Number of Patients Screened	**:**	
No. Patients Screen failed	**:**	
No. of Patient Randomized	**:**	
No. of Active Patients in the study	**:**	
No. Of Patients completed the study	**:**	
No. of drop-out patients	**:**	
No. of patients who withdrew consent	**:**	
No. of Patients Withdrawn by PI	**:**	
If the subject is Withdrew consent or Withdrawn by PI, state the reason:_____		
Duration of Study	**:**	
Date of Monitoring Visit	**:**	

Reason for Monitoring	:	☐ Routine ☐ For Cause (State Reason) ☐ SAE reported ☐ Protocol Violation/Deviation ☐ Other _____
Was Monitoring done previously for this study?	:	☐ Yes ☐ No If Yes, date of last monitoring_____
Are the facilities appropriate?? ☐ Yes ☐ No	:	Comment:
Are Informed Consent of Recent Version used? ☐ Yes ☐ No	:	Comment:
Is the used ICF approved by IEC, DUPMCH? ☐ Yes ☐ No	:	Comment:
Whether consent has been taken from all patients? ☐ Yes ☐ No	:	Comment:
Whether appropriate vernacular consent has been taken? ☐ Yes ☐ No	:	Comment:
Are protocols of recent version used? ☐ Yes ☐ No	:	Comment:
Is it approved by IEC? ☐ Yes ☐ No	:	Comment:
Any Adverse event found? ☐ Yes ☐ No	:	Comment:
Was the SAE informed to IEC within 24 hours of occurrence, if any? ☐ Yes ☐ No	:	Comment:

Has Any death occurred?	:	Comment:

☐ Yes ☐ No		
Any protocol Non-Compliance/Violation observed? ☐ Yes ☐ No	:	Comment:
Are all Case Record forms up to date? ☐ Yes ☐ No	:	Comment:
Are Storage of data and investigational products are secured properly with restricted access? ☐ Yes ☐ No	:	Comment:
Are Investigational product dispensing and accountability correct? ☐ Yes ☐ No	:	Comment:
Is Investigational product stored properly at correct temperature? ☐ Yes ☐ No	:	Comment:
Are there any changes in study personnel? ☐ Yes ☐ No	:	Comment:

Number of participants monitored during this visit?

Duration of the visit?

How well are participants protected? ☐ Good ☐ Fair ☐ Not Good

Any other Relevant Observations:

Comments of the monitor:

Duration of Visit:___Hours **Starting from:** **To:**

IEC, DUPMCH Monitoring Team	**Name**	**Sign and Date**
1		
2		
3		
4		
Present Study Team Members	**Name**	**Sign and Date**
1		
2		
3		

ANNEXURE 13: FORMULAE TO DETERMINE THE QUANTUM OF COMPENSATION IN THE CASES OF CLINICAL TRIAL RELATED INJURY OR DEATH

1. **Formula in case of clinical trial related death:**
   Compensation = (B x F x R)
   / 99.37 Where,
   B = Base amount (i.e. 8 lakhs)
   F = Factor depending on the age of the trial subject as per table given on page no(based on Workmen Compensation Act)
   R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the trial subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

   (a) 0.5terminallyillpatient(expected survival not more than(NMT)6months)
   (b) 1.0 Patient with high risk (expected survival between 6to24months)
   (c) 2.0 Patient with moderate risk
   (d) 3.0 Patient with mild risk
   (e) 4.0 Healthy Volunteers or trial subject of no risk.

   However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs should be given.

2. **Formula in case of clinical trial related injury (other than death):** For calculation of quantum of compensation related to injury (other than death), the compensation shall be linked to the criteria considered for calculation of compensation in cases of death of the trial subject as referred to in section of this Schedule. The quantum of compensation in case of Clinical Trial related SAE should not exceed the quantum of compensation which would have been due for payment in Case of death of the trial subject since the loss of life is the maximum injury possible. As per the definition of SAE, the following squeals other than death are possible in a clinical trial subject, in which the trial subject shall be entitled for compensation in case the SAE is related to clinical trial.

   i. **A permanent disability:** In case of SAE causing permanent disability to the trial subject, the quantum of compensation in case of 100% disability shall be 90% of the compensation which would have been due for payment to the nominee (s) in case of death of the trial subject.

   The quantum for less than 100% disability will be proportional to the actual percentage
   disability the trial subject has suffered.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = (C x D x 90) / (100 x 100)

Where:

D = Percentage disability the trial subject has suffered.

C = Quantum of Compensation which would have been due for payment to the trial subject's nominees) in case of death of the trial subject.

ii. **Congenital anomaly or birth defect:** The congenital anomaly or birth defect in a baby may occur due to participation of anyone or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

(a) Stillbirth;
(b) Early death due to anomaly;
(c) No death but deformity which can be fully corrected through appropriate intervention;
(d) Permanent disability (mental or physical).

The compensation in such cases would be a lump sum amount such that if that amount is kept by way of fixed deposit or alike, it shall bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The quantum of compensation in such cases of SAE shall be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to sub-clause (c) and (d) of this clause to any child, the medical management as long as required shall be provided by the Sponsor or his representative which will be over and above the financial compensation.

iii. **Chronic life-threatening disease; and**

iv. **Reversible SAE in case it is resolved**

In case of clinical trial related SAE causing life-threatening disease and reversible SAE in case it is resolved, the quantum of compensation would be linked to the number of days of hospitalization of the trial subject. The compensation per day of hospitalization shall be equal to the wage loss. The wage loss per day shall be calculated based upon the minimum wage of the unskilled worker (in Delhi).

Since, in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant, etc. The compensation per day of hospitalization in such case shall be double the minimum wage.

Accordingly, following formula shall be applicable for determination of compensation:

Compensation = 2 X W X N.

Where,

W = Minimum wage per day of the unskilled worker (in Delhi) N = Number of days of hospitalization

Factor (F) for calculating the amount of compensation

Age	Factor
Not more than...	
16	228.54
17	227.49
18	226.38
19	225.22
20	224.00
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52

45	**169.44**
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

ANNEXURE 14: STUDY PROGRESS REPORT

Project Title Staff / Student Project

1. Approval No.	**:**	
2. Principal Investigator	**:**	
3. Department	**:**	
4. Guide/Co-Investigator	**:**	
5. Department	**:**	
6. Time Since IEC Approval	**:**	
7. Status of Research	**:**	
8. Report of the work done since its inception with particular emphasis on the following	**:**	
• Material & Methods	**:**	
• Material Procedure: Yes /No	**:**	
• Permission Procured: Yes /No	**:**	
• Funding Status: Applied / Procured / NA, give details	**:**	
9. Total Participants / Sample entered / Consented/prepared	**:**	_____
10. Sample size achieved	**:**	
11. Participants Withdrawn from the Studies	**:**	Yes / No, if Yes give details _____
12. Data Collection	**:**	Yes / No / Partially Completed
13. Data Analysis	**:**	Yes /No

Principal Investigator Co-Investigator/Guide

Date: Date:

14. Conclusions and Major results Derived

15. Serious Adverse Event if any with details

16. Problems Encountered Solutions

17. Manuscript Writing: In Progress/Completed

18. List of research publications and paper based on work done of project

19. Remarks of the Guide : Satisfactory / Not Satisfactory

20. On completion of the research please provide the following

A brief abstract describing the study.
Details of unanticipated problems involving risk to the participants or other since beginning of the project and measures employed.
Blank copies of all current consent / Assent forms.

21. Undertaking:

21.1 I /We, the undersigned, give an undertaking to the following effect with regard To (STUDYTITLE)_____

_____

_____

agree with the above information given to the best of my/our knowledge, and does not infringe upon any, copyright , property, or personal right of any third party.

_____

_____

Principal Investigator
Date:

Co-Investigator/Guide
Date:

ANNEXURE 15: CONFLICT OF INTEREST DISCLOSURE FORM

I wish to inform_____Interest that I hold under the categories noted. **The conflict of interest** may be considered potential or actual when exercising decisions and actions in my role as a voting member within the IEC, DUPMCH.

Conflict of Interest

A conflict of interest exists in any situation when a person has a financial interest, a private, personal or familial interest, a business interest sufficient to influence, or appear to influence, the impartial exercise of duties or professional judgments.

Please tick the categories that apply to your area of conflict of interest with name of service below:

Conflict of Interest Definitions	✓
Financial Interest	
The term financial interest means anything of monetary value, including but not limited to	
• Salary or payment for services (for example: consulting fees and honoraria);	
• Equity interests (for example shares, share options and other owner ship interests);	
• Gifts;	
• Allowances, forgiveness of debts, interests in real estate, or personal property, dividends, rents, capital gains; and	
• Intellectual property rights (for example: patents, copyrights and royalties from these rights).	
Personal Interest A staff member has a personal interest in a matter if his or her spouse or partner, or other person in his or her family, or person with whom there is a close friendship, could be advantaged or disadvantaged, by any decision that the member either can make, or does not make, or is in a position to influence.	

Business Interest	
A member will have a business interest in a company seeking to do research at DUPMC if he or she;	
• Is a director of the Company:	
• Is an owner of, or partner in the Company:	
• Has a significant shareholding (equal to or greater than 20% shareholding) in the Company:	
• Has a close personal or familial relationship with a person who is an owner or partner, or significant shareholder in the Company.	
Please detail the Conflict of Interest you wish to disclose:	
Please detail action you propose to reduce, mitigate, or eliminate the conflict of interest:	

Name of the IEC, DUPMCH Member (please print)	**Role in the Committee**
Signature	**Date**
Proposed action to address Conflict of Interest. **(This Section to be completed by Chairperson of the IEC, DUPMCH)**	

Approved action:	
Declined action (and reason for declined):	
Alternative action required to manage conflict of interest (detail below):	
Name of the Chairperson	
Signature of the Chairperson	**Date**

Copy to the member disclosing conflict of interest. Original is to be maintained by IEC, DUPMCH office.

ANNEXURE 16: IEC, DUPMCH SELF-ASSESSMENT FORMAT

Sr. No	Item Description	Yes	No	Don't Know	Remarks if any
	EC as a whole				
1	Does the IEC, DUPMCH policy describe the procedure of selecting the members?				
2	Is there a specified term described to hold the Appointment for its member mentioned in the policy?				
3	Does every meeting of IEC, DUPMCH have the complete quorum as specified?				
4	Is the Chairperson of IEC, DUPMCH a non-affiliated member of your organization?				
5	Does IEC, DUPMCH describe the resignation procedure of its member?				
6	Does IEC, DUPMCH obtain the confidentiality agreement from members at the time of induction?				
7	Does IEC, DUPMCH Maintain the list of their members with their updated CVs?				
8	Does IEC, DUPMCH hold a dedicated office with required infrastructure and staff for its functioning?				
9	Does IEC, DUPMCH organize the training programme to update the knowledge and functioning of its members?				
10	Does IEC, DUPMCH have process to eliminate Conflict of Interest?				
11	Does IEC, DUPMCH SOP contain the specific scope, Objectives, activities, organization, infrastructure and funding aspects?				
12	Is your IEC, DUPMCH SOP regularly revised?				
13	Is functioning of IEC, DUPMCH strictly based on SOP mentioned?				
14	Does IEC, DUPMCH have specified submission guidelines made available to PI for their study protocols?				
15	Is there a specified format for proposal submission as per IEC, DUPMCH guidelines?				

16	Does IEC, DUPMCH involves in registration of trials and biomedical and health research with CTRI and CDSCO?				
17	Does IEC, DUPMCH have specified ICF and PIS formats?				
18	Does IEC, DUPMCH SOP specify the fee structure for the trials submitted?				
19	Does IEC, DUPMCH maintain the records of Minutes of the Meetings?				
20	Is there a fixed schedule of periodic meetings & are the records of attendance for the same maintained?				
21	Is the proposal submitted by PI checked for its Completeness along with the essential annexure attached duly signed by P.I. with date?				
22	Is IEC, DUPMCH strict with the submission of amendments by the PI?				
23	Does IEC, DUPMCH monitor/inspect/Audit the trials conducted as mentioned in SOP?				
24	Does IEC, DUPMCH SOP mention about Periodic Progress and Site Visits to monitor the trials?				
25	Is IEC, DUPMCH SOP based on ICH-GCP E6 (R_2), New Drugs and CT Rules 2019 and ICMR 2017 guidelines?				
26	Is IEC, DUPMCH an independent body?				
27	Does IEC, DUPMCH SOP address the guidelines to be followed for research in vulnerable population?				
28	Does IEC, DUPMCH have Soft Copy and Hard Copy of the records in its office?				
29	Does the IEC, DUPMCH SOP mention about approval and completion of the project?				
	For Individuals				
1	Do you regularly attend IEC, DUPMCH meetings?				
2	Do you know your role in IEC, DUPMCH?				
3	Do you actively involve yourself in review process of protocols by IEC, DUPMCH?				
4	Do you prepare for IEC, DUPMCH meeting prior i.e. with reading documents etc.?				
5	Do you feel that you could improve with better involvement?				

ANNEXURE 17: CHECKLIST FOR CLINICAL TRIAL DOCUMENTS SUBMITTED FOR IEC, DUPMCH REVIEW

(14 hard copies and a CD of all documents listed below)

Protocol Title:	
Principal Investigator:	
Type of Submission	Initial/Amendment
IEC, DUPMCH Submission Number and Date	

SR. NO	MANDATORY DOCUMENTS	YES	NO	NA
1	IEC, DUPMCH Processing Fee			
2	Submission Covering Letter duly signed by the Principal Investigator			
3	Study Protocol			
4	Investigator Brochure (IB)			
5	Patient Information Sheet (PIS) & Informed Consent Forms (ICFs) in English, Hindi and arati (and if require any other language)			
6	Translational Certificates for Hindi and arati (Back Translation certificate whenever applicable)			
7	Final Version of Case Record Form (CRF)			
8	Recruitment Procedure; advertisement, notices (if applicable)			
9	Patient Instruction card, diary, etc. (if applicable)			
10	DCGI Approval Letter/DCGI Submission Letter			
11	Insurance Policy and Certificate/Indemnity certificate (If applicable)			
12	Final Version of Clinical Trial Agreement (CTA)/Memorandum of Understanding (MoU)			
13	Undertaking by the PI			

SR. NO	MANDATORY DOCUMENTS	YES	NO	NA
14	Brief CV, MRC and GCP certificate of Investigator duly signed and dated			
15	Clinical Trial Registry – India (CTRI) Registration Certificate			
Documents Submitted: Complete Incomplete will submit on ……				
Remarks, if any:				
Receiver Name, Sign & Date: **(IEC, DUPMCH Secretariat)**				

+

ANNEXURE 18: TEMPLATE FOR INFORMED CONSENT DOCUMENT FOR PARTICIPANTS' PARENTS FOR RESEARCH INVOLVING CHILDREN/MINORS

(This template is for either clinical trials or clinical research)
(Language used throughout form should be at the level of a local student of class 6th/8th)

[YOUR INSTITUTIONAL LETTERHEAD]

[Informed Consent Form for Parents of Children (*having X condition/with Y disorder etc. as applicable as per your research*)]

Name the group of individuals for whom this parental consent is written.

[Name of Principal Investigator]

[Name of Organization]

[Title of the Research Study]

[Participant Initials/ Code]

This Informed Consent Form has two parts:

Information Sheet (to share information about the study with you)

Certificate of Consent (for signatures if you agree that your child may participate)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

1. **Introduction**
2. **Purpose**
3. **Type of Research Intervention if any**
4. **Why your child is chosen for the study?**
5. **Is your child's participation compulsory?**

(Include the following section only if the protocol is for a clinical trial:)

6. **Information on the Trial Drug [Name of Drug]**

---

7. **Procedures and Protocol**

Unfamiliar Procedures: (Explanation about randomization, blinding, placebo, rescue medications/therapy, allocation concealment etc. if applicable)

Process Steps to be followed: (Explanation about biopsy, blood sample collection, anesthesia requirements etc, infection control practices etc.)

8. **How long would the study continue?**
9. **What side effects could be foreseen to happen to your child in this study?**
10. **What if something goes wrong with your child?(Risks)**
11. **What Discomforts may your child feel during course of the study?**
12. **(Explain about the possible disturbance in behavior that may arise due to needle prick etc.)**
13. **What Benefits would your child avail?**
14. **What all reimbursements would be provided to your child?**
15. **Is your child's data Confidential?**
16. **How would the results of the study be communicated?**
17. **Could your child withdraw from the study in between?**
18. **What are alternatives if your child does not participate?**
19. **Whom to Contact?**

PART – II Informed Consent Form for Participant's Parent (ICFP)

(Tick √ or × in boxes against each point).

I have been invited to have my child participate in research of (Title of Study)	
I have read the foregoing information, or it has been read to me.	
I have had the opportunity to ask questions about it and any questions that I have asked	
I have been answered to my satisfaction.	
I consent voluntarily for my child to participate as a participant in this study.	

Print Name of Participant:_____
Print Name of Parent or Guardian:_____
Signature of Parent or Guardian:_____
Date (DD/MM/YYYY):_____

If illiterate

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness: _____ AND Thumb print of parent
Signature of witness: _____
Date:_____

Statement by the researcher/person taking consent
(Tick √ or × in boxes against each point).

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands the Study procedures.	
I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by the parent have been answered correctly and to the best of my ability.	
I confirm that the individual has not been coerced into giving consent for his/her child's participation, and the consent has been given freely and voluntarily.	

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent:_____
Signature of Researcher /person taking the consent: _____
Date (DD/MM/YYYY):_____
An Informed Assent Form will/will not be completed

ANNEXURE 19: TEMPLATE FOR INFORMED ASSENT DOCUMENT FOR RESEARCH INVOLVING CHILDREN/MINORS

[Informed Assent Form for Children_____]

[Name of Principle Investigator]:
[Name of Organization]:
[Title of Research Study:]
[Subject Initials/Identifier/Code]:

Part 1: Information Sheet

Introduction:

Purpose: Why this research? :
Why are you selected? :
Is it compulsory to do this? :
I have checked with the child and they understand that participation is voluntary --- (initial of researcher)(to be filled by researc | | | |

(Applicable to Clinical Trials Only)
Information on the Trial Drug

[Name of Drug]: What is this drug and what do you know about it?

Include the following section only if the protocol is for a clinical trial:

1) Give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) Provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial.

……
…

Procedures: What is going to happen to you?
I have checked with the child and they understand the procedures---------- (initial of researcher)(to be filled by investigator) | | | |
Risks: Is this bad or dangerous for me?
Explain any risks using simple, clear language.

Discomforts: Will it hurt?
If there will be any discomforts state these clearly and simply. State that they (children) should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

I have checked with the child and they understand the risks and discomforts---------- (initial of researcher)(to be filled by investigator) | | |

Benefits: Is there anything good that happens to me?
Describe any benefits to the child.

I have checked with the child and they understand the benefits---------- (initial of researcher)(to be filled by investigator) | | |

Reimbursements: Do I get anything for being in the research?

Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research? These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context.

Confidentiality: Is everybody going to know about this?
Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

Compensation: What happens if I get hurt?
Describe to the ability of the child to understand and explain that parents have been given more information.

Sharing the Findings: Will you tell me the results?
Describe to the ability of the child to understand that the research findings will be shared in a timely fashion but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly,
i.e. in a book, journal, conferences, etc.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

Whom to Contact: Who can I talk to or ask questions to?

List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

I understand that this research include
(add experimental aspects i.e. needle prick, survey, biopsy, lab investigations etc., details about follow-up visits, maintenance of patient diary by self/parents)

I have read this information (or had the information read to me)

I have had my questions answered and know that I can ask questions later if I have them. I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below.
_____(Initial led by child/minor)

<u>Only if child assents</u>:

Print name of child:_____
Signature of child: _____
Date:_____

***If illiterate**:*
A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions.

I confirm that the individual has given consent freely.
Print name of witness (not a parent):_____ AND Thumb print of
Participant Signature of witness: _____
Date: _____

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions.

I confirm that the individual has given assent freely.

Print name of researcher: _____
Signature of researcher: _____
Date: _____

--

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that why and how the study would be done and his/her role as a subject.

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent & Signature

_____

- ✓ **Copy provided to the participant_____(initialed by researcher/assistant)**
- ✓ **Parent/Guardian has signed an informed consent__Yes___No___(initialed by researcher/assistant)**

ABBREVIATIONS

SOP	Standard Operating Procedure
DUPMCH	Dr. Ulhas Patil Medical College and Hospital
IEC, DUPMCH	Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital
ICMR	Indian Council of Medical Research
HRRP	Human Research Review Panels
IEC	Institutional Ethics Committee
CV	Curriculum Vitae
MoU	Memorandum of Understanding
ICD	Informed Consent Document
CTA	Clinical Trial Agreement
NGO	Non Governmental Organization
MRC	Medical Research Council
CTRI	Clinical Trials Registry-India
CDSCO	Central Drugs Standard Control Organization
PIS	Patient Information Sheet
ICF	Informed Consent Form
AV	Audio Visual
EC	Ethics Committee
CoI	Conflict of Interest
AE	Adverse Event
SAE	Serious Adverse Event
CT	Clinical Trial
CRF	Case Report Form
PI	Principal Investigator
ICH-GCP	International Conference on Harmonization- Good Clinical Practice
DCGI	Drug Controller General of India
IW	Impartial Witness
LAR	Legally Acceptable Representative

5.8 Approve a new / revised SOP

- The final version will be presented to the Chairperson for review and approval.
- The authors, reviewers and the Chairperson sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date from where by the SOP will be implemented.

5.9 Ensure Implementation, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- The approved SOPs will be distributed to the IEC members according to the distribution list. *AX 04/SOP 01/V1*.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat of the IEC in the office of Institutional Ethics Committee.
- When the revised version is distributed, all the IEC members will be requested to destroy the earlier version. One copy of the earlier version will be filed centrally in the file entitled 'Past SOPs of the IEC' by the Secretariat of the IEC in the IEC office.
- The Secretariat will review the SOPs at least once in every 3 years and record the dates of review on the SOP Master file.
- As per the findings and opinion of the Secretariat, the Member-Secretary will inform the Chairperson about the result of review process.
- The Chairperson will inform the IEC members at a regular meeting about the recommendation regarding review of SOPs or about the request for revision in the SOP made by a member. If members agree, the Chairperson will constitute one or more SOP teams as per need to amend/ modify SOPs as per 5.2.The SOP team will write and review SOP as per procedure described in 5.3. The SOPs will be distributed, discussed, approved as per procedure described in 5.7 and 5.8. The SOPs will be implemented, distributed and filed as per 5.9

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.

IEC members	Individuals serving as regular members of the Institutional Ethics Committee. The Board has been constituted in accordance with the IEC membership requirements set forth in Schedule Y (20th January 2005 and changed according to amendment in Schedule Y (30 January 2016, 8th February 2016)
SOP Team	A Team of members selected from the Institutional Ethics Committee including the Member Secretary and at least two more members who oversee the creation, preparation, review and periodic revision of the Institutional Ethics Committee SOPs.
Master SOP files	An official collection of the Standard Operating Procedures (SOPs) of Institutional Ethics Committee accessible to all staff, IEC/ members, auditors and government inspectors as a paper copy with an official stamp and the signature of either member secretary/ chairperson of the IEC on the first and the last page of the SOP booklet. Photocopies made from these official paper versions of the SOP cannot be considered official.
Past SOPs of the IEC	A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations.
Effective date	The date of approval of the SOPs signed and dated by the Institutional Ethics Committee- Chairperson and subsequently the SOP is implemented from that date.

7. References

[1] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016)

[3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethical_guidelines.pdf* (last accessed 31st August 2016)

[4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) *http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm* (last accessed 31st August 2016)

8. Annexure

Annexure 1	*AX 01/SOP 01/V1*	List of SOPs of IEC
Annexure 2	*AX 02/SOP 01/V1*	Template for Standard Operating Procedures
Annexure 3	*AX 03/SOP01/V1*	Document History of the SOP
Annexure 4	*AX 04/SOP01/V1*	Log of the IEC members receiving SOPs
Annexure 5	*AX 05/SOP01/V1*	Request for Formulation of a new SOP/ revision of an SOP
Annexure 6	*AX 06/SOP01/V1*	Logs of SOP Recipients

Annexure 1

AX 01/SOP 01/V1

List of SOPs of Institutional Ethics Committee

No	Title of the Standard Operating Procedures (SOPs)	SOP Code
1	Preparation of Standard Operating Procedures (SOPs) for the Institutional Ethics Committee (IEC)	SOP 01/V1
2	Constituting the Institutional Ethics Committee.	SOP 02/V1
3	Confidentiality / Conflict of Interest Agreements	SOP 03/V1
4	Selection and Responsibilities of Independent Consultants	SOP 04/V1
5	Management of Protocol Submissions	SOP 05/V1
6	Initial Review of Submitted Protocol	SOP 06/V1
7	Expedited Review	SOP 07/V1
8	Review of Resubmitted Protocols	SOP 08/V1
9	Review of Amended Protocol/Protocol related documents	SOP 09/V1
10	Continuing Review of Study Protocols	SOP 10/V1
11	Review of Study Completion Reports	SOP 11/V1
12	Protocol Deviation/Non-Compliance/Violation	SOP 12/V1
13	Management of Premature Termination of the Study	SOP 13/V1
14	Review of Serious Adverse Event (SAE) Reports	SOP 14/V1
14(A)	Constituting SAE Subcommittee	SOP 14(A)/V1
15	Site Monitoring Visit	SOP 15/V1
16	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 16/V1
17	Conduct of Emergency Meeting	SOP 17/V1
18	Maintenance of Active Project Files	SOP 18/V1
19	Archiving and Retrieving Documents	SOP 19/V1
20	Maintaining Confidentiality of IEC Documents	SOP 20/V1
21	Responding to Research Participant's Request or Complaint	SOP 21/V1
22	Exemption from the Ethics Review for Research Projects	SOP 22/V1
23	Request for Waiver of Written Informed Consent	SOP 23/V1
24	Reviewing proposals involving vulnerable Populations	SOP 24/V1.1

Annexure 2

AX 02/SOP 01/V1

Template for Standard Operating Procedures

Effective date: *aa/bb/cccc*	*Short Title*	Page p of q
SOP *xx/Vy*		
Institutional Ethics Committee DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.		

Title: Title which is self-explanatory and easily understood

SOP Code: SOP xx/Vy
Effective date: aa *bb cccc*
Authors: xxxxxxxxx **Signature with date** ----------
Reviewed by: xxxxxxxx **Signature with date** ----------
Approved by: xxxxxxxxx **Signature with date** ----------

Table of Contents:

No.	Contents	Page No.
1	Purpose	X
2	Scope	X
3	Responsibility	X
4	Flow Chart	X
5	Detailed Instructions	X
6	Glossary	X
7	References	X
8	Annexure	X

Main Text:

1. **Purpose:** *Summarizes and explains the objectives of the procedure.*
2. **Scope:** *States the range of activities that the SOP applies to.*
3. **Responsibility:** *Refers to person(s) assigned to perform the activities involved in the SOP*
4. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*
5. **Detailed instructions:** *Describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*
6. **Glossary:** *Clarifies uncommon or ambiguous words or phases by explanation.*
7. **References:** *Lists sources of the information given in the SOP*
8. **Annexure:** *Documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand*

Annexure 3

AX 03/SOP 01/V1

Document History of the SOP

Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change

Annexure 4

AX 04/SOP01/V1

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Annexure 5

AX 05/SOP 01/V1

Request for Formulation of new SOP/ Revision of an SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP xx/Vy	
Title:	
Details of problems or deficiency in the existing SOP	
Need to formulate an entirely new SOP (i.e. SOP not existing previously)	
Identified by:	Date *(DD/MM/YYYY)*:
Discussed in Institutional Ethics Committee Meeting held on:-	
SOP revision required: ☐ Yes	☐ No
Action required: ☐ New SOP to be formulated ☐ SOP to be deleted ☐ SOP to be amended ☐ No action to be taken ☐ Any other (Please specify): If no action to be taken, please state reasons	
If action recommended: SOP team: [1] Member-Secretary: [4] [2] [5] [3] [6]	

Date -SOP re-finalized:	
Date -SOP approved:	
Date- SOP becomes effective:	
Signature with date Chairperson, IEC	

Annexure 6

AX 06/SOP 01/V1

Log of SOP recipients

No.	Name of the Recipients	Designation	SOP code number	No. of Copies	Date
1	XXXXXX	XXXXX			
2	XXXXXX	XXXXX			
3	XXXXXX	XXXXX			
4	XXXXXX	XXXXX			
5	XXXXXX	XXXXX			

Title: Constituting Institutional Ethics Committee

SOP Code: SOP 02/V1 dated 22nd August 2016

Authors:

Dr. Devendra R. Chaudhari (Member Secretary, IEC) 01/09/16

Reviewed by:

Dr. Rahul Prakash Bhavasar (Member , IEC) 01.09.201

Approved by:

01/9/2016

Dr. Ravindrakumar Bakal , Chairperson, IEC

(Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	11
7	References	11
8	Annexure	11

1. Purpose

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the Institutional Ethics Committee (IEC).

2. Scope

The SOP applies to all activities performed by the Institutional Ethics Committee.

3. Responsibility

It is the responsibility of the Institutional Ethics Committee members and the Secretariat to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

4. Flow Chart

No.	Activity	Responsibility
1	Composition of the Institutional Ethics Committee	Head of the Institute ,Chairperson, IEC Members and Secretariat
2	Membership requirements	Head of the Institute , Chairperson,
3	Tenure of Membership	Chairperson, IEC Members and Secretariat
4	Initiation of the process of appointment	Secretariat
5.	Appointment of new members	Head of the Institute
6.	Resignation and disqualification of members	IEC Members and Secretariat
7.	Conditions of appointment	IEC Members and Secretariat
8.	Selection and appointment of Chairperson	Head of the Institute
9.	Quorum requirements	IEC Members and Secretariat

5. Detailed Instructions

5.1 Ethical basis

- 'Institutional Ethics Committee' (IEC) first established in 1987, is an institutional IEC of DR. Ulhas Patil Medical College and Hospital, Jalgaon kh. The IEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India and all dissertation projects (postgraduate students :MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), research projects of undergraduate students (Indian Council for Medical research studentship) and investigator initiated research studies which are self funded and those funded by Research Society of DUPMC Hospital.

- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of research projects involving human participants.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The IEC also seeks to be informed, as appropriate, by other IEC approving other trial sites and researchers of the impact of the research it has approved. The IEC is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004), 59th WMA General Assembly, Seoul, October 2008.
- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human rights and Biomedicine (1997).
- The IEC will work according to its established Standard Operating Procedures based on the Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization- Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006). The mandate will be
  a. To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
  b. Provide public assurance of that protection.
- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.
- The IEC will review only those projects which are carried out in this institution by the staff members and students of the institution.
- The IEC will also review projects which are carried out by institutional members in collaboration with other national or international institutions.

5.2 Composition of the Institutional Ethics Committee

- The IEC will be established by the **Head of the Institution (HOI)**.
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 and a maximum of 15 members. The members should be a mix of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- The members will have differing backgrounds as this would promote complete and adequate review of research activities commonly conducted at DR. Ulhas Patil Medical College and Hospital, Jalgaon kh.
- The IEC will have representation that is varied in terms of gender, age and social background.
- The Composition shall be as follows:
  - ✓ Chairperson (who will be a member not -affiliated to the institution)
  - ✓ One Member Secretary
  - ✓ One Joint Member Secretary (appointed if necessary)
  - ✓ One or more persons from basic medical science area
  - ✓ One or more clinicians from various institutes
  - ✓ One legal expert or retired judge
  - ✓ One social scientist/ representative of non-governmental agency
  - ✓ One philosopher, ethicist or theologian
  - ✓ One or more lay person from community
- The IEC may appoint an alternate legal expert, lay person from community and a social scientist who can take part in the IEC activities in absence of regular members from the above specified categories. The requirement, appointment and terms of membership will be the same as described below in sections 5.3 to 5.9.
- The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (*AX 03/SOP 03/V1)* and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote

5.3 Membership requirements

- The Head of the Institute (HOI) is responsible for appointing new committee members.

  The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the HOI.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.

- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration (Refer to *AX 01/SOP 03/V1 and AX 02/SOP 03/V1* Confidentiality / Conflict of Interest Agreements).

- The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision (Refer to *AX 01/SOP 03/V1 and AX 02/SOP 03/V1* Confidentiality / Conflict of Interest Agreements). Members will be required to sign a confidentiality agreement at the start of their term. (Refer to SOP *AX 01/SOP 03/V1 and AX 02/SOP 03/V1* Confidentiality / Conflict of Interest Agreements)

5.4 Tenure of Membership.

- The tenure of Institutional Ethics Committee members will be for a continuous period of two (2) years from the date of appointment.

- The IEC secretariat will initiate the process of filling up the forthcoming vacancies two months prior to the end of tenure of a member, The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list provided by the IEC or otherwise. The retiring member will be eligible to be appointed for the new tenure any number of times.

5.5 Appointment of new members and alternate members

a) The IEC members will be appointed by the HOI. New members will be appointed under the following circumstances:

   1. When a regular member completes his/ her tenure.
   2. If a regular member resigns before the tenure is completed.
   3. If a regular member ceases to be a member for any reason including death or disqualification.
   4. To fulfill the membership requirements as per 5.2 of this SOP

b) New members will be identified by the Chairperson according to the requirement (i.e. as per the composition specified in Section 5.2 of this SOP), membership requirement (Section 5.3 of this SOP) and provided the potential member fulfils the conditions of appointment as defined in 5.8 of this SOP after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

c) Alternate member(s) will be appointed if deemed necessary by the HOI. The alternate member(s) will substitute a regular member and attend the meeting in absence of the regular member(s). The criteria for selection and membership requirements mentioned in 5.3, 5.4, 5.5 (b), 5.6, 5.7, 5.8 and 5.12 will be applicable to alternate members.

5.6 Resignation and Disqualification of Members.

- Resignation: An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

- Disqualification for conduct unbecoming of an IEC member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an IEC member.

  (i) The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.

  (ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.

  (iii) The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.

  (iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

- Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows:

  (i) The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC.

  (ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting

  (iii) A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson

  (iv) The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

- The Chairperson or Member-Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC

5.7 Conditions of appointment

Members and Independent consultants will be appointed to the IEC if they accept the following conditions.

- Willingness to publicize his/her full name, profession and affiliation.
- Willingness to record reimbursement received for work and expenses incurred, related to the IEC assignment and make these records available to IEC and/ or general public on request.
- Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

5.8 Training of the IEC Members in Research Ethics

- An individual selected as a new member of the IEC will be required to attend two meetings as an 'Observer' before being inducted as a member of the IEC
- Member-secretary or an IEC member will provide an introductory training to the new member.
- The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC Members to the Institutional faculty members.
- The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

5.9 Hierarchy

- There will be one Chairperson, one Member Secretary. A Joint Member Secretary may be appointed amongst the members if necessary.
- The Chairperson will be the head of the committee.
- The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
- Other IEC members will be regular committee members with equal ranking.
- The Chairperson will be appointed by the Head of the Institute,

- The Member-secretary, Joint Member-Secretary (if necessary) will be elected by and from amongst the IEC members for 2 years term. These may be re-elected any number of times. Should they resign or be disqualified, the IEC members will elect a replacement for another term.

5.10 Chairperson

- The Chairperson will be appointed by the Head of the Institute,
- The Chairperson will not be affiliated to the institution.
- The Chairperson will be responsible for conducting committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will preside over all elections and administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IEC at various meetings and forums.
- The Chairperson will sign documents and communications related to IEC functioning.
- The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with IEC SOPs
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.11 Secretariat

[1] The Secretariat will be composed of the IEC Member Secretary, IEC Joint Member Secretary (where applicable), the scientific officer/s the administrative Officer/s and other administrative supporting staff.

[2] The Member Secretary and the Joint Member Secretary (appointed if necessary) will be elected by and from amongst the committee members.

[3] The administrative staff of the Secretariat will be appointed by the IEC and they will be supervised by the Member Secretary.

[4] The Secretariat shall have the following functions.

Functions of the Member secretary

1. To receive research proposals
2. To organize an effective and efficient tracking procedure for each proposal received.
3. To prepare, maintain and distribute of study files.
4. To schedule and organize IEC meetings
5. To prepare and maintain meeting agenda and minutes.
6. To maintain IEC documentations and to archive them.
7. To sign documents and communications related to IEC functioning.
8. To communicate with the IEC members and applicants/ investigators.

9. To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
10. To arrange for training of personnel and IEC members.
11. To organize the preparations, review, revision and distribution of SOPs and guidelines.
12. To provide necessary administrative support for IEC related activities to the Chairperson.
13. To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
14. To receive fees and issue official receipts for the same.
15. To delegate various responsibilities to appropriate and authorized individuals
16. To ensure adherence of IEC functioning as per SOPs

✓ **Functions of the Joint Member Secretary** (whenever appointed)

The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

✓ **Functions of the Administrators** (*AX 01/SOP 02/V1*)

1. To support the Member Secretary in executing functions of the IEC.
2. To perform any other functions as instructed by Member Secretary/ Chairperson.

5.12 Roles and Responsibilities of IEC members

- To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation.
- To monitor Serious Adverse Event reports and recommend appropriate action(s)
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality / Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- To provide an updated CV when requested for by the IEC secretariat

- To carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary.
- To assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs

5.13 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of at least 5 members one regular member (preferably one pharmacologist), the social worker, a clinician, the lay person and the legal expert besides Member Secretary and Chairperson. (As per the Schedule Y – version dated 20th January 2005, for review of each protocol the quorum of IEC should be at least 5 members - one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community).

5.14 Honorarium to the Members/ Independent Consultants

Reimbursement of traveling expense, honorarium for attending the IEC meetings and /or honoraria may be given to the IEC members/ office bearers/ Independent consultants and any other person authorized by the IEC. ***5.15 Responsibilities of the Institutional Ethics Committee***

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.
- The Committee will keep all information submitted to them confidential specially the proprietary information.
- The Committee will maintain concise but clear documentations of its views on the research proposal.
- The Committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.
- The Committee will participate in activities that promote ethical research in the institution and community.
- The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, IEC members in ethical research.

5.16 Prepare an annual activity report of the IEC for submission to the Head of the Institute

- The Secretariat will make a yearly activity report for submission to the Head of the Institute which will include the following elements:
    a. A quantitative evaluation of the activities of the committee in a year

b. The list of the proposals reviewed in a year
c. Status of each study proposal

6. Glossary

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC/ information and documents
IEC	Institutional Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial (at sites which do not have EC/EC not functional as per Schedule Y) and to provide public assurance of that protection.
Independent Consultants	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

7. References

[1] World Health Organization, Operational Guidelines for IEC that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/- last accessed 31st August 2016) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016)

[2] CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm (last accessed 31st August 2016)

[3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st August 2016)

[4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm (last accessed 31st August 2016), amendment 30th January 2016)

[5] European Convention on Human rights and Biomedicine (1997).http://conventions.coe.int/treaty/en/treaties/html/164.htm (last accessed 31st August 2016)

8. Annexure

Annexure 1 *AX 01/SOP 02/V1* IEC Administrative staff: Working rules

8. Annexure

Annexure 1 AX01/SOP 02/V2 IEC Administrative staff: Working rules

Annexure 1

AX 01/SOP 02/V2

The IEC Administrative Staff: Working Rules

[1] The hierarchy of the administrative staff will be as follows:

Administrative manager who will overall look after the management of the IEC and under him/her will be one deputy Manager each for IEC. For each IEC committee, there will be one executive assistant to Member secretary working under deputy Manager. One separate executive assistant to Member Secretary will be allotted for SAE Sub-committee who will work directly under the Administrative Manager. Two attendants will work for both the committees as well as SAE subcommittee; each one will be supervised by Deputy Manager. All these administrative staff will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The decisions regarding need for appointment, eligibility criteria, job profile and remuneration will be taken by the IEC members attending a regular IEC meeting and will be recorded in minutes.

[2] The administrative staff will be appointed by conducting formal interviews (to be conducted by 2 to 3 members of the IEC, designated by the Chairperson and one teaching staff (Professor/Associate Professor / Assistant Professor) of the institution who is not affiliated to IEC).

[3] The terms and conditions of the appointment shall be as follows:

The appointment will be on temporary basis. A monthly stipend will be given. The amount of stipend will be decided by the IEC members. Since the posts are not DUPMC posts, the DUPMCJ service rules will not apply to them. The appointed staff will not get benefit of DUPMCJ employees. They will not get any preferential treatment and will not have right to the posts advertised by DUPMCJ.

[4] Duties of the Administrative Manager:

- Overall management of both the IECs.
- Supervising the duties of the deputy Manager.
- Supervising the duties of Executive assistant to Member secretary of SAE subcommittee.

- Attending the meetings of both the committees as well as SAE subcommittee.
- Maintain the attendance chart as well as effective of all the administrative staff monthly.
- Managing all the financial expenses of both the committees.
- All communication to the investigators in case of change in any policy of IEC.
- All the communication of finance with the DUPMCJ must be co-ordinated by Administrative Manager along with signature of Member Secretary.
- All correspondence to the regulatory authorities in regards to SAE compensation issue.
- Overall co-ordination of the activities related to audits/registrations with national and international bodies.
- Confirming about the completion of the archival procedures.
- Issuing permission of retrieval of archived documents along with the Chairperson.
- Confirmation that all the data (hard copy and soft copy) are maintained and are up to date.
- To co-ordinate for the upgrading or modification in the software/hardware of the committee.
- Managing the SOPs of the IEC, its revision as well as uploading the recent approved SOP on the institutional website as and when needed.
- Interacting with the investigators in regards to financial queries.
- Assisting the Chairperson/Member Secretary to reply any inquiry put forth by the regulatory authority/investigator/any person.
- Performance of other duties assigned by the Chairperson/Member Secretary.

[5] Duties of the Deputy Manager/s:

- Correspondence with the IEC members and external experts
- Correspondence with the investigators
- Arranging the IEC meetings
- Assisting in preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Getting work done from the Executive assistants to Member Secretary.

- Keeping a track that all the software data/soft copies are in place and complete.
- Analysis of the data if assigned by the Chairperson/Member Secretary/Committee member.
- Performance of other duties assigned by the Chairperson/Member Secretary/Administrative Manager.

[6] Duties of the Executive Assistant/s to Member Secretary:

- Receiving all research proposals (hard copy as well as soft copy)
- Numbering the proposals.
- Forwarding all proposals to committee members for review.
- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all committee meetings.
- Inviting experts from relevant therapeutic areas to the scheduled meetings.
- Notification of review outcome to investigators of research proposals.
- Preparation and circulation of minutes (within 14 days of the meeting).
- Reviewing project related correspondence submitted by the investigators to the IEC.
- Retention and safekeeping of all records and documentation.
- Updating of the soft copies and the software data entry.
- Sending the reminder letters, if any.
- Performance of other duties assigned by the Chairperson/Member Secretary/Administrative Manager/Deputy Manager.

[7] Duties of the (SAE) Executive Assistant/s:

- Receiving all SAE/CIOMS/SUSAR reports of ongoing studies.
- Forwarding all these documents to the Member Secretary/ subcommittee members for review.
- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all SAE sub-committee meetings.
- Inviting experts from relevant therapeutic areas to the scheduled meetings if required.
- Notification of review outcome to investigators.
- Preparation and circulation of SAE sub-committee minutes (within 7 days of the meeting).

- Retention and safekeeping of all records and documentation.
- Updating of the soft copies and the software data entry.
- Sending the reminder letters, if any.
- Performance of other duties assigned by the Chairperson/Member Secretary/Administrative Manager/Deputy Manager.

[8] Duties of the Attendant/s or Helper/s:

- Assisting the secretariat in arranging the IEC meetings
- Dispatching sets of study documents to IEC members and external experts
- Receiving the study related documents from and dispatching the IEC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Correspondence with the IEC members and external experts
- Performance of other duties assigned by the Chairperson/Member Secretary/Administrative Manager/Deputy Manager/Executive assistants.

[9] The administrative staff will report to the Chairperson and/or Member Secretary.

[10] The office timing for the Administrative manager will be Monday to Friday 10.00 am to 5.00 pm and Saturday 10.00 am to 1.30 pm, for the *Deputy Manager and executive* assistants will be Monday to Friday 9.00 am to 4.30 pm and Saturday 9.00 am to 1.00 pm. The timing for Office Assistant will be Monday to Friday 8.30am to 4.30 pm and Saturday 8.30 am to 1.00 pm.

[11] The staff will avail 15 casual leaves and 15 privileges leave every year by making an application. The number of leaves granted per year cannot be accumulated or carried forward to next year. A new staff member will be allowed to avail a casual leave 6 months after joining and privilege leave after completing one year. Leave applications will be maintained in the personal file of the staff members. The decision regarding granting a long leave to the staff will be taken at a regular IEC meeting by the IEC members.

[12] The pay revisions will be made according to the recommendations of the IEC. The recommendations regarding pay revisions will be discussed at a regular IEC meeting and will be recorded in minutes. The final decision regarding pay revision will be taken by the DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL, the accounts of the IEC.

Title: Confidentiality / Conflict of Interest Agreements

SOP Code: SOP 03/V1 dated 22nd August2016

Authors:

Dr. Devendra R. Chaudhari (Member Secretary, IEC)	01/09/16

Reviewed by:

Dr. Rahul Bhavsar (Member, IEC)	01.09.2016

Approved by:

	01/09/2016 Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	3
6	Glossary	4
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide a form of Confidentiality/ Conflict of Interest Agreement and identify who should read, understand, accept, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. Scope

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Institutional Ethics Committee (IEC)

3. Responsibility

- It is responsibility of each IEC member reviewing research project or attending IEC meeting to read, understand, accept and sign the agreement contained in the confidentiality / Conflict of Interest Form. The form should be read, understood, accepted and signed by each IEC member at the beginning of the tenure of his/her membership
- It is the responsibility of each and every newly-appointed member of IEC to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning ethical and/or scientific review tasks and prior to his/her attending IEC meetings held to review research studies to protect the rights of study participants.
- It is the responsibility of the guest/observers intending to attend an IEC meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form prior to attending an IEC meeting and/or before ethical review tasks with the Institutional Ethics Committee are commenced.
- It is the responsibility of the Independent Consultant (IC) to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the IEC and/or attending a meeting of IEC.
- The Secretariat will ensure that the Confidentiality / Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests or observers for IEC meetings or Independent Consultants prior to attending an IEC meeting, accessing IEC documents or undertaking review processes (as applicable) and notify to the IEC Chairperson. The Secretariat will file signed Confidentiality/ Conflict of Interest Agreement forms in the files entitled 'Confidentiality /Conflict of Interest Agreement Forms'

4. Flow chart

No.	Activity	Responsibility
1.	Provide appropriate forms to IEC member, Guest attendees, Observers, Independent	IEC Secretariat

	Consultant	
2	Read the text carefully and thoroughly	IEC members / guest attendees / observers / Independent Consultant
3	Ask questions, if any	IEC members / guest attendees / observers / Independent Consultant
4	Sign and indicate consent	IEC members / guest attendees / observers / Independent Consultant
5	Keep the Agreement in mind.	IEC members / guest attendees / observers / Independent Consultant
6	File the signed forms	IEC secretariat

5. Detailed instructions

5.1 Read the text carefully and thoroughly.

- The appropriate Confidentiality and / or Conflict of Interest Agreement Form will be provided to the IEC member, Guest attendee, Observer and Independent Consultant
- Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC members and before he/she starts attending IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form - *AX 01/SOP 03/V1 and AX 02/SOP 03/V1,* carefully and thoroughly.
- Every observer or guest for IEC meeting: before initiating ethical review and / or before commencement of the meeting will read the Confidentiality / Conflict of Interest Agreement Form *AX 03/SOP 03/V1* carefully and thoroughly
- Every Independent Consultant before initiating ethical review and / or before commencement of IEC meeting will read the Confidentiality / Conflict of Interest Agreement Form -*AX 04/SOP 03/V1* carefully and thoroughly
- IEC member, Guest attendee, observer, Independent Consultant will fill up the details such as name, designation and official address.

5.2 Ask questions, if any.

- If any of the IEC members/Guests /observers for IEC meetings/Independent Consultants have any doubts, need clarifications or if any part or sentences is not clear, they will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and / or clarifications. If any further explanations are needed they can be provided by the Chairperson / Legal expert/other IEC members.

5.3 Sign to indicate consent.

- The newly appointed IEC member, before the beginning of their tenure, Guests /observers for IEC meetings, Independent Consultants will sign and date the document before a member of the Secretariat.
- They will give the signed form back to the Secretariat
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality /Conflict of Interest Agreement Form.
- The secretariat will provide IEC member, Guests or observers for IEC meetings, Independent Consultants a photocopy of the Confidentiality /Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement by their signature.
- The Secretariat keeps the original copies of the signed Agreements at the Institutional Ethics Committee office in the files entitled 'Confidentiality/Conflict of Interest Agreement file for members, guests, observers, Independent Consultants (IC)'
- The Secretariat will store the file in a secure cabinet with limited key holders.

5.4 Keep the Agreement in mind.

- The IEC members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants must implement the clauses of the signed Confidentiality Agreement Form as in *AX 01/SOP 03/V1* , *AX 03/SOP 03/V1* and *AX 04/SOP 03/V1* respectively.

6. Glossary

Confidentiality	The nonoccurrence of unauthorized disclosure of information
Confidentiality Agreement	Sometimes called Secrecy or Non-disclosure agreement An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

	There are three key elements in this definition: financial interest, official duties, and professional interest. A conflict of interest occurs when: • An individual's private interest differs from his or her professional obligations to the institute. • Professional actions or decisions occur that an independent observer might reasonably question. • A conflict depends upon situation and not on the character or actions of the individual. • Potential conflicts of interest must be disclosed and managed as per policy.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000 (Geneva 2000 *www.who.int/tdr/publications/publications/-* last accessed 31st August 2016).

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016).

8. Annexure

Annexure 1	*AX 01/SOP 03/V1*	Confidentiality Agreement Form for IEC members
Annexure 2	*AX 02/SOP 03/V1*	Conflict of Interest Agreement Form for IEC Members
Annexure 3	*AX 03/SOP 03/V1*	Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings
Annexure 4	*AX 04/SOP 03/V1*	Confidentiality Agreement for Independent Consultants

Annexure 1

AX 01/SOP 03/V1

Confidentiality Agreement Form for IEC Members

In recognition of the fact, that I _____

_____

(Member's name, and his/her affiliation) herein referred to as the "undersigned", have been appointed as a member of the IEC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical

manner, adhering to the highest standards of care as per the national and local

and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on

merits and not as an advocate or representative of a legal province, territory or

nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both

and ethical aspects of research protocols involving human subjects and make a

determination and the best possible objective recommendations, based on the merits of the

submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to retain the trust and

confidence of the communities in the protection of the rights and well-being of research

participants;

The undersigned, as a member of the IEC, is expected to meet the same high standards of

ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary

provided to the Undersigned in conjunction with the duties as a member of the IEC. Any

written information provided to the undersigned that is of a Confidential, Proprietary or

Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets

("information") in trust or confidence and agrees that it shall be used only for

purposes and shall not be used for any other purpose or disclosed to any third party.

Written Confidential information provided for review shall not be copied or retained. All

Confidential information (and any copies and notes thereof) shall remain the sole property of

of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or

Proprietary information belonging to a third party in fulfilling this agreement. Furthermore,

the Undersigned confirms that his/her performance of this agreement is consistent with the

institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

*Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the **IEC**. A copy will be given to you for your records.*

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, _____ (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

_____ _____

Signature Date

Annexure 2

AX 02/SOP 03/V1

Conflict of Interest Agreement Form for IEC Members

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

_____ _____

Signature **Date**

Annexure 3

AX 03/SOP 03/V1

Confidentiality Agreement Form

For Guest / Observer Attendees to IEC Meetings

I, _____ (name), understand that I am being allowed to attend the Institutional Ethics Committee meeting scheduled on _____ at _____am/ pm as a Guest. The meeting will be conducted in the _____, DR. Ulhas Patil Medical College and Hospital. In the course of the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

_____ **Signature of the Guest**	_____ **Date**
_____ **Chairperson of IEC**	_____ **Date**

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the IEC -Chairperson and me.

_____ _____

Signature of the Guest **Date**

Annexure 4

AX 04/SOP 03/V1

Confidentiality Agreement Form for Independent Consultants / Independent Monitors

I,_____

_____ (Name and Designation) as a non-member of Institutional Ethics Committee (IEC) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any

person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

_____ **Signature of the recipient**	_____ **Date**
_____ **Chairperson of IEC**	_____ **Date**

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

_____ _____

Signature **Date**

Annexure 5

AX 05/SOP 03/V1

Confidentiality Agreement Form for Institutional Funding Societies

I,_____

_____ (Name and Designation) as a member/ staff of Funding Society (DJST/DDF/Research Society) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

_____ **Signature of the** member/ staff of Funding Society	_____ **Date**

Chairperson of IEC-I	**Date**
Chairperson of IEC-II	**Date**

I, _____ (name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

_____ _____

Signature **Date**

Title: Selection and Responsibilities of Independent Consultants

SOP Code: SOP 04/V1 dated 22nd August 2016

Authors:

Dr. Devendra R. Chaudhari (Member Secretary, IEC) 01/09/16

Reviewed by:

Dr. Dr. Rahul Prakash Bhavasar (Member, IEC) 01.09.2016

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	3
6	Glossary	4
7	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for engaging the expertise of a professional as an Independent Consultant (IC) to the Institutional Ethics Committee (IEC), Mumbai

2. Scope

If the Chairperson, Member Secretary or the IEC determine that a study involves procedures or information that is not within the collective expertise of the IEC members, the Chairperson/ Member Secretary on behalf of the IEC will invite individual(s) with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to that/ those available with the IEC.

3. Responsibility

Upon the advice or recommendation of the secretariat or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special Independent Consultant(s) (IC) and be endorsed by the Chairperson for the given project.

4. Flow chart

No.	Activity	Responsibility
1	Maintenance of a specialty-wise list/ roster of ICs	IEC Secretariat
2	Recommendation of a name of one or more IC(s)	IEC Member, Member Secretary or Chairperson
3	Selection and Appointment of IC(s)	Chairperson
4	Invitation to IC(s) on behalf of IEC	Chairperson/ Member-Secretary
5	Co-ordination with IC(s) for fulfilling administrative requirements	IEC Secretariat
6	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC , Chairperson
7	Reviewing documents pertaining to research project,	IC
8	Termination of the Services	Member-Secretary/ Chairperson/

5. Detailed instructions

5.1 Recommendation of a name of an Independent Consultant

- The IEC will select a panel of IC(s) from the different specialties of Medicine and the chairperson will issue an appointment letter to the IC(s)
- An IEC member/ Chairperson may suggest that the opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by the IEC or from outside the roster; if during the review process of any given research project he/she is of the opinion that the project involves procedures or information that is not within the area of collective expertise of the IEC members,
- The IEC will decide regarding the need for acquiring the services of IC(s) and identify and select the IC(s) to be invited from within or outside the roster of ICs maintained by the IEC secretariat; based on area of expertise, independence and availability.
- The Chairperson/ Member Secretary on behalf of the IEC will invite IC(s) selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through any mode of communication
- The Secretariat will request IC to declare competing interests, if any and sign a confidentiality agreement. The Secretariat may obtain and retain a copy of the updated curriculum vitae of ICs in the IEC office for records and future reference
- The Secretariat will maintain and provide a specialty-wise roster of Consultants

5.2 Selection of Independent Consultants

- The final approval from the IEC Chairperson to refer the project to the specified Independent Consultant will be taken by the Secretariat. If any IEC member disagrees with the selection of the Independent Consultant, the procedure in 5.1 will be repeated.

5.3 Co-ordination with Independent Consultants for fulfilling administrative requirements

- The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to IC(s) *AX 04/SOP 03/V1* -for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ IEC members.

5.4 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement document.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.

- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).
- The Independent Consultant is expected to implement the clauses of the signed Confidentiality Agreement Form *AX 04/SOP 03/V1*.

5.5 Reviewing documents pertaining to research project

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) *AX 02/SOP 06/V1* to the IC(s) after Confidentiality and Conflict of Interest documents have been signed by IC and Chairperson and received by the IEC. The IC(s) will be provided with a copy of 'Guidelines for review' *AX 05/SOP 06/V1*. The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed in the IEC meeting when the concerned Project is being discussed.
- If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the IC in writing. Additional Information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairperson or Member-secretary may invite IC(s) the IC(s) to attend an IEC meeting for providing additional information or clarifications that may be sought by IEC members or Chairperson. However, the IC will not participate in the decision making process on the project
- Termination of the Services
- As the IC(s) is appointed for a particular task or project and the services of IC(s) get automatically terminated once the final decision regarding the project is taken by the IEC. The IEC will document the termination of the services of IC by providing a letter thanking the IC for the services rendered. If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

6. Glossary

Independent Consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

7. Annexure

Annexure 1 *AX 01/SOP 04/V1* Study Assessment Form for Independent Consultant

Annexure 1

AX 01/SOP 04/V1

Study Assessment Form for Independent Consultant

IEC Protocol Number:	
Protocol Title:	
Comments on the protocol:-	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	
Remarks:	☐ **Recommend approval** ☐ **Recommend approval after incorporation of changes suggested** ☐ **Recommend disapproval (Please state Reasons)** ☐ **Any other (Please specify with reasons)**
Name of the Consultant reviewing the project:	

Signature with Date:

Title: Management of Protocol Submissions

SOP Code: **SOP 05/V1 dated 22nd August 2016**

Authors:

Dr. Rahul Prakash Bhavasar (Member, IEC) 01.09.2016

Reviewed by:

Dr. Devendra R. Chaudhari (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	References	6
7	Annexure	6

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC.

2. Scope

Protocol submissions include:

- Submission of Research Project for Initial Review of the Protocol and related documents
- Resubmission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to Continuing Review of Approved Protocols
- Submission of written communications for Protocol Termination

3. Responsibility

It is the responsibility of the IEC secretariat to receive the submission packages, record, distribute for review and get the submission packages approved by the IEC, as well as to deliver the review results to the protocol applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages	IEC Secretariat
2	Initial Review Application	IEC Secretariat
3	Resubmission of Protocols with Corrections	IEC Secretariat
4	Protocol Amendments	IEC Secretariat
5	Annual Continuing Review of Approved Protocols	IEC Secretariat
6	Protocol Completion	IEC Secretariat

5. Detailed instructions

5.1 Receive submitted packages

The Principal Investigator can submit research proposal to the Institutional Ethics Committee office for review and approval under any of the 5 sections mentioned below.

- Initial Review Application
- Resubmission of Protocols with corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Protocol Termination

5.2 Initial Review Application

5.2.1 Check for submission items

- The Secretariat will check the hard copies and soft copies of following items

1. A completely filled IEC Project Submission Application Form for Initial Review *AX 1-A/SOP 05/V1 / AX 1-B/SOP 05/V1*
2. A checklist for contents of a submitted package *AX 02/SOP 05/V1*
3. Delegation of Responsibilities of Study team *AX 03/SOP 05/V1*
4. Document Receipt Form *AX 04/SOP 05/V1*
5. Four sets of the proposal (One original and 3 sets of Xerox copies)

5.2.2 Verify contents of Submitted Package

The Secretariat will:

- Use the checklist for contents of a submitted package, *AX 02/SOP 05/V1* to verify that items listed and ticked in the checklist are present in the packet
- Check if all relevant and applicable forms and documents are in the submitted package being submitted to the IEC office. The correctness of the IEC application form will be assessed at the time of submission by the secretariat. Verify the completeness of the contents of the protocol submitted package to include the following documents:

✓ Project submission application form for initial review

✓ Letter to Member Secretary/ Chairperson

✓ Protocol, to include

a) Title of the Protocol
b) Name and contact details of Principal Investigator
c) Name and contact details of Sponsor
d) IND Number (if applicable)
e) Abstract (summary/synopsis)
f) Study Methodology - Type of Protocol (screening, survey, phase of clinical trial), Objectives, Inclusion/Exclusion Criteria, Withdrawal or discontinuation Criteria, Schedule and Duration of Treatment, Modes of Treatment Studied, Procedures, Activity plan / Timeline, Efficacy or Evaluation Criteria (Response/Outcome), Safety Parameters Criteria (Toxicity), Analysis (methods)

✓ Amendments to protocol (if any)

✓ Informed consent document in English (as per sample format in Annex *AX 06/SOP 05/V1*)

✓ Informed consent document in Regional languages

✓ Back translations of Informed consent documents

✓ Translation and Back translation certificate

✓ Informed Consent Document (ICD) or Amendments to the Informed consent document (if any)

✓ Case Record Form

✓ recruitment procedures: advertisement, notices, letters to doctors (if applicable)

✓ Patient instruction card, identity card, diary etc. (if applicable)

✓ Investigator Brochure

✓ Regulatory permissions (as applicable)

- DCGI approval
- Investigator's Undertaking to DCGI
- FDA marketing/manufacturing license for herbal drugs
- Health Ministry Screening Committee (HMSC) approval
- Bhabha Atomic Research Centre (BARC) approval
- Genetic Engineering Advisory Committee (GEAC) approval
- Administrative sanction from the head of the Institution in case of studies involving collaboration with other institutions.
- A copy of Administration sanction from the head of the Institution for sending the samples to laboratories outside DUPMCH

✓ Brief Curriculum Vitae of all the study team members

✓ GCP training certificate (within 5 years) of Principle investigator and study co-ordinator.

✓ Investigator's agreement with Sponsor

✓ Memorandum Of Understanding (MOU)for collaborative studies

✓ Insurance policy

✓ Ethics Committee clearance of other centers (if applicable)

✓ Institutional Stem cell committee approval

✓ Any additional document(s), as required by IEC (Cheque/ Demand Draft drawn in the name of "Diamond Jubilee Society Trust, Seth GS Medical College and KEM Hospital" towards payment of IEC processing fees, as decided upon by the IEC from time to time)

5.2.3 Complete the submission process

The Administrative Officer/ any one designated by IEC will

- Stamp the receiving date on the first page/last page of the covering letter and initial his/her name on the receiving documents.

- Make a photocopy of the completed document receipt form *AX 04/SOP 05/V1* and return the original copy of the *AX 04/SOP 05/V1* to the applicants for their records.
- Keep the copies of the submitted documents with original signatures in the protocol "Submission" file.
- Number the project file as EC/PHARMA Number (00)/ year (00) for pharmaceutical sponsored studies and EC/GOVT Number (00)/ year (00) for Government/ Government-agency sponsored studies, EC/Number (00)/year (00) for thesis and EC/OA Number (00) for non-sponsored / OA-Other Academic studies e.g. EC/PHARMA 01/07 will indicate pharmaceutical sponsored study with number 01 of the year 2007.

5.2.4 Dispatch and Store the received packages

The Administrative Officer will

- Prepare **4** sets of a protocol package containing completed application form *AX 1-A/SOP 05/V1 / AX 1-B/SOP 05/V1*, protocol related documents along with checklist *AX 02/SOP 05/V1* and send three sets to the IEC members along with a copy of Project Assessment Form for Initial Review *AX 02/SOP 06/V1*.
- Store the appropriately labeled original protocol packages in the cupboard in the Institutional Ethics Committee office.

5.3 Resubmission of Protocols with corrections

- For resubmitted protocol, the Principal Investigator will submit a soft copy and one hard copy of the Protocol and related documents.
- The Secretariat will verify the completeness of the documents and reconfirm that the copy contains the modification highlighted with respect to the earlier protocol submitted mentioning the justification for the modification. The protocol related documents incorporating the change in the protocol are also submitted and verified by the Secretariat.)
- The Secretariat will perform the steps 5.2.2 & 5.2.3 as mentioned in initial review application. The protocol related documents which do not require to be changed and are already submitted for the Institutional Ethics Committee office during initial review are not required to be submitted again.

5.4 Protocol Amendments

- The Principal Investigator will submit a hard copy and soft copy of the Protocol and related documents (as per SOP 09/V1)
- The Secretariat will verify the completeness of the checklist for contents of a submitted package
- The Secretariat will check that the copy contains a list of modifications and the modifications are highlighted with respect to the earlier protocol submitted mentioning the justification for the modification.
- The Chairperson will decide whether to

- Take a decision regarding allowing or disallowing amendments without review by a selected group of IEC members or review by IEC members at an IEC meeting for minor administrative amendments
- Carry out review by a one or more member(s) selected by the Chairperson. The selected members are normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time. In this case, the decision on approval /disapproval will be taken by the Chairperson and / or Member secretary after receiving the comments of the designated members and will be informed to all the IEC members in the forthcoming meeting.
- Consider for discussion at the full board meeting

5.5 Annual Continuing Reviews of Approved Protocols

- The Principal Investigator will submit one copy (soft and hard) of Annual Study Report and related documents (as per SOP 10/V1).
- The Secretariat will verify the completeness of the Continuing Review Application Form *AX 01/SOP 10/V1*, Progress report/Request letter for extension of approval of the project. The Administrative Officer will sign and date the documents.

5.6 Protocol Completion

- The Principal Investigator will submit one copy (hard and soft) of Study Completion Report and related documents (as per SOP 11/V1)
- The Secretariat will verify the completeness of the Study Completion Report Form *AX 02/SOP 11/V1* filled by the Principal Investigator

6. Reference

[1] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

7. Annexure

Annexure 1-A	*AX 01-A/SOP 05/V1*	Project submission application form for initial review for Industry and Government sponsored studies.
Annexure 1-B	*AX 01-B/SOP 05/V1*	Project submission application form for initial review for all academic (non sponsored) studies.
Annexure 2	*AX 02/SOP 05/V1*	Checklist of protocol submission
Annexure 3	*AX 03/SOP 05/V1*	Delegation of Responsibilities of Study team
Annexure 4	*AX 04/SOP 05/V1*	Document Receipt Form
Annexure 5	*AX 5/SOP 05/V1*	Guidelines for Investigators
Annexure 6	*AX 06/SOP 05/V1*	Sample format of an Informed Consent Document
Annexure 7	*AX 07/SOP 05/V1*	Format for submission of an Informed Consent Document for Genetic Studies

Annexure 1-A

AX 1-A/SOP 05/V1

Project submission application form for initial review

for Industry and Government sponsored studies

- Please fill in the details in legible hand writing
- Tick √ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

IEC Protocol No.

Title of the protocol

_____

_____

_____

_____

_____

	Name	**Designation & Qualifications**	**Department & Institution**	**Signature**
Principal Investigator				
Co-Investigator				
Co-Investigator				

Co-Investigator				
Co-Investigator				
Co-Investigator				
Coordinator				
Coordinator				

(If additional collaborators attach details and letter of Consent by the collaborator (s) on a separate page.)

Please attach brief curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) ☐ Attached

Non-sponsored (Investigator Initiated) **study** ☐ **Sponsored study** ☐

1.Sponsor Information :

1. Indian a) Government ☐ Central ☐ State ☐
   b) Private ☐

2. International ☐ Government ☐ Private ☐ UN agencies ☐

3. Industry ☐ National ☐ Multinational ☐

Contact Address of Sponsor:

_____

_____

If sponsor is from out of India, contact address in India:

_____

_____

2.Total Budget : Rs._____
Research Fund will be deposited in: DJST DDF Research Society Other

If other, please specify_____

Please give details of allocation of budget in an attachment. Attached

Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐

Any Other ☐

Please specify_____

Clinical: Single center ____ Multicentric ____ (Attach a list of centers)

If multicentric, how many centres : India _____ and Globally :_____(attach list of countries)

3. Clinical Trials:

Medicine /Vaccines/Device/Herbal Remedies : (Tick the appropriate boxes)

i. Does the study involve use of :

Medicine ☐ Devices ☐ Vaccines ☐

Indian Systems of Medicine/ ☐ Any other ☐ NA ☐

If other, specify_____

ii. Is it approved and marketed

In India ☐ UK & Europe ☐ USA ☐ NA ☐

Other countries, specify _____

(Tick the appropriate box/option)			
iii. Does it involve a change in use, dosage, route of Administration?	Yes	No	NA
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?	Yes	No	NA
If yes, Date of permission :----------			
If No, whether DCGI's /Any other Regulatory Authority's Permission applied for?	Yes	No	NA
iv. Is it an Investigational New Drug (IND)?	Yes	No	NA

If yes, IND No:			
a) Investigator's Brochure submitted	Yes	No	NA
b) *In vitro* studies data	Yes	No	NA
c) Preclinical Studies done	Yes	No	NA
d) Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐			
e) To submit package insert in case test drug is already marketed in India Attached ☐			
e) Are you aware if this study/similar study is being done else where ? If Yes, Specify details ---------- ----------	Yes	No	
f) Whether DCGI's permission for testing IND obtained? If yes, Date of permission : __	Yes	No	NA
g) whether DCGI's permission for testing IND applied for?	Yes	No	NA
h) For Ayurvedic or herbal formulation, a copy of the marketing/manufacturing license issued by the FDA to the company to be submitted	Yes	No	NA
4. **Protocol of the proposal** – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale (Submit as attachment)			
5. Research participants **selection:** i. Number of research participants at this centre : Number of research participants at other sites in India : Total number of research participants at all sites (in the world):			
ii. Duration of study : No. of visits :			
iii. Will research participants from both sexes be	Yes	No	NA

recruited			
iv. Inclusion / exclusion criteria given	Yes	No	
v. Type of research participants Volunteers ☐ Patients ☐ NA ☐			
vi. Vulnerable research participants ☐ Yes ☐ No ☐ NA pregnant women ☐ elderly ☐ mentally challenged ☐ fetus ☐ illiterate ☐ handicapped ☐ children ☐ captives ☐ terminally ill ☐ elderly ☐ seriously ill ☐ economically or socially backward ☐ dependent staff ☐ institutionalized employees ☐ students ☐ HIV ☐ Any other ☐ To specify_____			
6. Privacy and confidentiality i. Study involves - Direct Identifiers ☐ Indirect Identifiers/coded ☐ Completely anonymised/ delinked ☐			
ii. Confidential handling of data by staff	Yes	No	
7. Use of biological/ hazardous materials	Yes	No	NA
i. Use of fetal tissue or abortus	Yes	No	NA
ii. Use of organs or body fluids	Yes	No	NA
iii. Use of recombinant/gene therapy	Yes	No	NA
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No	NA
Iv. Use of pre-existing/stored/left over samples	Yes	No	NA
v. Collection for banking/future research	Yes	No	NA
vi. Use of ionizing radiation/radioisotopes **If yes,** has Bhaba Atomic Research Centre (BARC)	Yes	No	NA

approval for radioactive isotopes been obtained?	Yes	No	NA
Vii. Use of Infectious/biohazardous specimens	Yes	No	NA
Viii. Proper disposal of material	Yes	No	NA

8. Will any sample collected from the patients be sent abroad? **Yes** **No** **NA**

If yes

a) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons.....

Lab. Address:_____

If no,

b) test on samples be carried out:

In KEM ☐

Outside KEM ☐

If outside DUPMC, Address: _____

If Yes, specify with details of collaborators

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)

Yes ☐ No ☐ NA ☐

10. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for?

Yes ☐ No ☐ NA ☐

11. Consent : *Written ☐ Oral ☐ Audio-visual ☐ NA ☐

approval for radioactive isotopes been obtained?	Yes	No	NA
Vii. Use of Infectious/biohazardous specimens	Yes	No	NA
Viii. Proper disposal of material	Yes	No	NA

8. Will any sample collected from the patients be sent abroad? **Yes** **No** **NA**

If yes

a) Sample will be sent abroad because (Tick appropriate box):

Facility not available in India ☐

Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons.....

Lab. Address:_____

If no,

b) test on samples be carried out:

In KEM ☐

Outside KEM ☐

If outside DUPMC, Address: _____

If Yes, specify with details of collaborators

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)

Yes ☐ No ☐ NA ☐

10. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction from the Dean obtained/ applied for?

Yes ☐ No ☐ NA ☐

11. Consent : *Written ☐ Oral ☐ Audio-visual ☐ NA ☐

i. Consent form : (tick the included elements)

Understandable language	☐	Alternatives to participation	☐
Statement that study involves research	☐	Confidentiality of records	☐
Sponsor of study	☐	Contact information	☐
Purpose and procedures	☐	Statement that consent is voluntary	☐
Risks & Discomforts	☐	Right to withdraw	☐
Benefits	☐	Compensation for study related injury	☐
Compensation for participation	☐		
Benefits if any on future commercialization	☐ NA	☐	
Consent for future use of biological material	☐ NA	☐	

*If written consent will not be obtained, give reasons: _____

Whether applied for waiver of Consent: _____

ii. Who will obtain consent? PI/Co-PI ☐ Nurse/Counselor ☐
Research staff ☐ Any other ☐

	Yes	No	NA
12. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)			
13. Risks & Benefits:	Yes	No	NA
i. Is the risk reasonable compared to the anticipated benefits to research participants / community / country?			
ii. Is there physical / social / psychological risk / discomfort?	Yes	No	NA
If Yes, Minimal or no risk ☐			
More than minimum risk ☐			
High risk ☐			

iii. Is there a benefit

(a) To the research participants? Direct Indirect ☐

(b) Benefit to society ☐

	Yes	No	NA
14. Data Monitoring			
i. Is there a data & safety monitoring committee/ Board			

(DSMB)?			
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ IEC ☐ DSMB ☐	Yes	No	
iii. Is there a plan for interim analysis of data?	Yes	No	NA
vi. Are there plans for storage and maintenance of all trial ----------database?**IfYes,**forhowlong?	Yes	No	
15. Is there compensation for participation **If Yes,** Monetary ☐ In kind ☐ Specify amount and type: __	Yes	No	NA
16. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance company ☐ by any other ☐	Yes	No	NA
17. Do you have any conflict of interest in the present study? **(financial/non financial)** **If Yes, specify :**__ ----------	Yes	No	
18. Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC or IEC carried out by the Principal Investigator. (Information to be given: whether study is initiated, no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly in a separate sheet, if required)	☐		
19. Current Brief Curriculum Vitae (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator _ (Information required -age, designation and department, educational qualification, previous research experience in last five years)	(To be enclosed along with the form)		

(Information about GCP training of PI and co investigator)			
20. GCP training certificates of principal investigator and coordinators (mandatory only for drug and device trials not for observational studies)	(To be enclosed along with the form)		
21. Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India(CTRI)/ any other WHO platform registry _____ **Registration number:** _____ **If not registered, state the reason**_____	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2016, 8th February 2016), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2006), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996) while conducting the research study.

We also ensure that Principal Investigator / Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

Signature of Principal Investigator with date: _____

Signature/s with date of Co-investigators: 1._____

2._____ 3._____ 4._____ 5._____

Signature of coordinator: 1._____ 2._____

Forwarded by Heads of Department(s)

Signature/s with date of Heads of Department(s):

_____, _____, _____, _____

_____, _____, _____, _____

Stamp/Seal of the Department(s)

Annexure 1-B

AX 1-B/SOP 05/V1

Project submission application form for initial review

for all academic (non-sponsored) studies.

Please fill in the details in legible hand writing

Tick √ in the box for the appropriate answer/ Write NA if question is not applicable

IEC Protocol no. _____

Title of the project

_____
_____
_____
_____
_____

	Name	Designation	Department and Institution
Principal Investigator			
Co-Investigator			
Co-Investigator			
Co-Investigator			

Co-Investigator			

If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page.

Non-sponsored study ☐ Sponsored study ☐

If Non-Sponsored Study:

Type of study : Thesis/dissertation ☐ ICMR/KVPY ☐ Other Academic ☐

Duration of study _____ Approx. Completion date (MM/YY) _____

If sponsored,

Total Budget : Rs._____

From where is the study being funded

a) Research fund is being utilized from DJST ☐ Research Society ☐ Others ☐

If any other, please give details _____

1.Type of Study : Prospective ☐ Retrospective ☐ Cross-sectional ☐

Is the study observational/ Interventional? _____

If interventional, does the study involve any deviation from routine/standard practices?

_____

_

2. Does the study involve use of : Drug / Vaccine ☐ Device ☐ Alternative Medicine ☐

New Technique (surgical/PT/OT, etc) ☐ Diagnostic Kit/ Investigations ☐

If other, pleasespecify_____

_____

i) Is the test drug / device marketed in India Yes ☐ No ☐

ii) Does the test drug involve a change in use, dosage, route of administration?

Yes ☐ No ☐

If yes, please attach copy of DCGI permission.

If no, please attach copy of package insert/product insert.

3. Subject selection:

i) Number of subjects at this centre ☐ if multicentric, total number of subjects ☐

ii) Vulnerable subjects Yes ☐ No ☐ (If yes, tick the appropriate boxes)

pregnant women ☐ illiterate ☐ seriously/terminally ill ☐

children ☐ neonates ☐ mentally challenged ☐

elderly ☐ handicapped ☐ economically/socially backward ☐

institutional employees / students ☐ any other ☐

If other, please specify_____

4. Does the study involve use of		
i) fetal tissue or abortus	Yes ☐	No ☐
ii) organs or body fluids	Yes ☐	No ☐

iii) Gene therapy If yes, please submit a copy of Genetic Engineering Advisory Committee (GEAC) permission.	Yes ☐	No ☐
iv) ionizing radiation/radioisotopes If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission.	Yes ☐	No ☐
v) infectious / biohazardous specimens	Yes ☐	No ☐
vi) Will pre-existing/stored/left over samples be used?	Yes ☐	No ☐
vii) Will samples be collected for banking/future research	Yes ☐	No ☐
viii) Will any sample collected from patient be sent abroad? If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission.	Yes ☐	No ☐
ix) Is there any collaboration with any foreign lab., clinic or hospital ? If yes, please submit a copy of Health Ministry Screening Committee (HMSC) approval.	Yes ☐	No ☐
5. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.) If yes, kindly attach a copy for IEC review.	Yes ☐	No ☐
6. Is there compensation for participation (traveling allowance)? If Yes, Monetary ☐ In kind ☐ Specify amount / type: _____	Yes ☐	No ☐
7. Are there any arrangements for compensation / treatment of trial related injury? If yes , by sponsor ☐ by investigator ☐ By insurance company ☐ by others ☐ Please submit a copy of the insurance policy if it is available.	Yes ☐	No ☐

8. Do you have any conflict of interest in the present study?

(financial / non – financial/ any other)

If yes, specify: .....

9. Is any other department involved in participant recruitment/investigation, but not co-investigators or collaborators ? Yes/No

If yes, specify .....

Name and signature of concerned HOD

.....

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of Principal Investigator: _____

Signatures of Co- investigators: 1._____ 2._____

3._____ 4. _____

Forwarded by Heads of Department(s) _____ _____

Stamp/Seal of the Department(s)

Please fill the form in legible handwriting or type the information.

Write 'Not Applicable' (NA) wherever necessary.

Incompletely filled form will not be accepted.

Annexure 2

AX 02/SOP 05/V1

Check List for Protocol Submission

Check List of Documents for Protocol Submission to the Institutional Ethics Committee to be filled in by the study team

Protocol submission for initial review

(Tick accordingly, compulsory documents have to be submitted by ticking in the box marked as 'Yes') * Compulsory documents for initial review.

Sr. No.	Document	Yes	No	Date by which it will be submitted, if pending	NA
1	*Project submission application form duly filled		—	_____	—
2	Approval of Departmental Review Board (DRB)(for thesis/dissertations proposals)				
3	*Letter to Member Secretary/ Chairperson		—	_____	—
4	*Summary of protocol (in not more than 500 words)		—	_____	—
5	*Protocol		—	_____	—
6	*Informed consent document in English		—	_____	—
7.	*Informed consent documents in Regional languages (Total No:-)		—	_____	—
8.	Back translation of Informed Consent Documents		-	_____	
9	Translation and Back translation certificates		-	_____	
10	*Case Record Form		—	_____	—
11	*Research participants recruitment procedures: advertisement, notices (If applicable)		—	_____	—
12	*Patient instruction card, identity card, diary etc.				
13	*Research participants Questionnaire/s (If applicable)		—	_____	—
14	*Investigator Brochure		—	_____	—

15	*Insurance certificate and policy		—	———————	—
16	*Investigator's undertaking to DCG(I)		—	———————	—
17	DCG(I) approval [if DCGI approval is awaited, the same is mentioned in the covering letter to the IEC]				
18	*Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for collaborator & Govt sponsored trials (draft if final not ready)		—	———————	—
19	FDA marketing/manufacturing license for herbal formulations/ nutraceutics				
20	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations				
21	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy				
22	a) Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy)				
	b) Administrative sanction from the Head of the Institution for the samples to be sent to outside DUPMC Hospital (one copy)				
23	*Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-ordinator) (one copy only)		—	———————	—
24	*Ethics Committee clearance of other centers (Total No _____)		—	———————	—
25	*Log of delegation of responsibility of the study team members - Sample Format Enclosed)		—	———————	—

26	*Document Receipt Form (one copy only)		—	———————	—
27	*Current Status of Ongoing Studies approved by IEC and IEC conducted by principal investigator (information may be submitted separately)		—	———————	—
28	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)				
29	*GCP training certificates of principal investigator and study co-ordinator for interventional clinical trial sponsored by pharmaceuticals companies (one copy only)				
30	Any other Documents submitted				

To be filled in by the IEC – Checklist for EC form:

1. Contact Address of Sponsor ☐
2. Total Budget ☐
3. Information on Clinical Trials —
4. Information on Protocol of the proposal ☐
5. Research participants selection —
6. Privacy and confidentiality —
7. Use of biological/ hazardous materials —
8. Consent —
9. Risks & Benefits —
10. Data Monitoring —
11. Compensation for participation —
12. Compensation for injury —
13. Statement on conflict of interest —

Annexure 3

AX 03/SOP 05/V1

Delegation of Responsibilities of Study team

Study title_____

_____

Name	Role	No.
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6
	Study co-ordinator *	7
	Study co-ordinator *	7
	Laboratory Technician	8
		9
		10

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor)

(Please place tick marks against assigned duties for each member in the following table)

Code	TASKS	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7	Role 8	Role 9	Role 10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										

H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug, , document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Annexure 4

AX 04/SOP 05/V1

Document Receipt Form for initial review

Protocol Number:	**Received number:**	**Submitted date:**
Protocol Title:		
Principal Investigator:		
Department		
Communication with the IEC :	**E-mail address** Phone Fax	
For office use only		
Documents submitted:	☐ Complete ☐ Incomplete, will submit on.....	
Documents to be submitted later :	☐ final signed clinical trial agreement ☐ informed consent form (Local 3rd Vernacular language) ☐ study budget ☐DCGI ☐ CTRI ☐GCP Training certificate ☐ Other sites EC permission ☐ Others.....	Check what documents are received later on. ☐ final signed clinical trial agreement ☐ informed consent form (Local 3rd Vernacular language) ☐ study budget ☐ DCGI ☐ CTRI ☐GCP Training certificate ☐Other sites EC permission ☐ Others.....
Received by (Name and signature) :		
Date on which documents received:		

Note: Please bring this receipt with you when you visit the office of the Institutional Ethics Committee.

Current Contact Details:

Institutional Ethics Committee (IEC),Department of pharmacology
Dr. Ulhas Patil Medical College and Hospital, Jalgaon, Khurd
Gat no. 315,316, 321, 305, Jalgaon khurd, Bhusawal Road NH6,JALGAON 425309.
TEL.NO. – 0257-2366657, 2366678, FAX NO. 0257-2366648
Email: ethicsdupmcj@gmail.com

Annexure 5

AX 05/SOP 05/V2

Guidelines for Investigators

1. All the studies qualifying as 'clinical research' need to be submitted for the Institutional Ethics Committees review.
2. An Investigator planning to conduct a research study involving human participants; **funded by Government agencies and Pharmaceutical companies** at DR. Ulhas **Patil** Medical College & Hospital, should seek permission of the **Institutional Ethics Committee(IEC)** before commencing a study.

   Research studies which are undertaken as **dissertation projects (postgraduate students :MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), research projects of undergraduate students** (Indian Council for Medical research studentship) and **investigator initiated** research studies which are **self-funded** and those funded by Research Society of DUPMC Hospital, will need an approval by the **Institutional Ethics Committee (IEC).**
3. Location and Office Address (current):

   Institutional Ethics Committee (IEC),
   Department of pharmacology
   Dr. Ulhas Patil Medical College and Hospital, Jalgaon, Khurd
   Gat no. 315,316, 321, 305, Jalgaon khurd, Bhusawal Road NH6,JALGAON 425309.
   TEL.NO. – 0257-2366657, 2366678, FAX NO. 0257-2366648
   Email: ethicsdupmcj@gmail.com
   The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC staff are as follows:

   Monday to Friday - 1.30 p.m. to 4.00 p.m.
   Saturday - 10.30 a.m. to 12.00 noon
   The office will remain closed on Sundays and all public holidays.
4. There will be no meetings held in the month of May and November (during college vacations). In case a meeting is to be held during vacation due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.

5. The clinical trial (Any investigation in human research participants intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy [ICH-GCP]) must be registered with the Clinical Trial Registry of India (CTRI) or any other WHO platform registry and a copy of the documentation of registration must be provided at the time of submission of a new study proposal for review.
6. The principal investigator(PI) and the study co-ordinator should be GCP trained before initiating the study and copies of the GCP training certificates (at least one) within the preceding five years should be provided to the IEC at the time of submission of a new study proposal / prior to initiation as applicable.
7. The IEC is currently following the version 4 dated 22nd August 2016 of the Standard Operating Procedures (SOPs), which are individual activity based and are 24 in number. The SOPs are available with the General Manager in the office of the IEC. An investigator may submit a request in writing for a hard copy/ an electronic version of the SOPs of the IEC.
8. The following steps need to be followed by investigators while communicating with the IEC:

I **Prior to approval of a research study**

a) **Submission of a New Study Proposal**

The Project Submission Application Form ***AX 1-A/SOP 05/V2 / AX 1-B/SOP 05/V2*** **with** Checklist of Protocol Submission ***AX 02/SOP 05/V2*** to be submitted is available at the IEC office. **Four** sets of project proposal (one original set and three sets of photocopies and soft copy of whole proposal [on CD]) should be submitted. For some general and administrative documents (specified in the Check List for Protocol Submission ***AX 02/SOP 05/V2***) only one copy can be submitted. Project proposals submitted to the office of the IEC **on or before 20th of every month will** usually be taken up for discussion at the next month's IEC meeting. Each set shall contain the documents mentioned in ***AX 02/SOP 05/V2*** on A 4 size paper arranged in a plastic file in the same order. Please use the following form and checklist available in the IEC office for submission of new study.

- Project Submission Application Form for Initial Review ***AX 1-A/SOP 05/V2 / AX 1-B/SOP 05/V2***
- Checklist for protocol submission ***AX 02/SOP 05/V2***
- Appendix I *(enclosed)* states regulatory permissions to be sought wherever applicable.

b) The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the ICMR 2006 Guidelines. The section should include the

following aspects which may be stated in the Ethics Section or elsewhere in the protocol:

- A statement saying that the study will be conducted in adherence to relevant national/international laws.
- Policy regarding autonomy (voluntariness, right to withdraw).
- Confidentiality
- Recruitment policy ensuring equitable enrolment.
- Protection of vulnerable participants.
- Process of obtaining informed consent.
- Policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.
- Policy regarding dissemination of data, presentation of data, publication.

c) An investigator is required to fill in all the details in the form ***AX 1-A/SOP 05/V2 / AX 1-B/SOP 05/V2*** **very** clearly in legible handwriting. **Incompletely filled forms / forms without signatures will not be accepted.**

d) The study proposals will be circulated after 20th of every month to the IEC members for review and discussed at the IEC meeting to be held in the following month.

e) For all projects sponsored by pharmaceuticals, the processing fees will be Rs. 50,000/ project (effective from 1st September 2109), for the Government sponsored projects, the processing fees will be Rs. 5,000 /project (effective from 1st September 2109) and for all academic (non- sponsored) projects the processing fees will be Rs. 500/-project (in hard cash) (effective from 10th October 2010). The processing fees shall be collected only once at the time of submission of the project. The sponsored projects fees will be accepted by cheque / demand draft drawn in the name of **'DR ULHAS PATIL MEDICAL COLLEGE', PAN no. AAATG1840Q.**

Duplicate copy of any document (for e. g. Permission letter, certificate, query letter) will be charged Rs. 200/- & the entire protocol will be charged Rs. 250/- for academic studies.

f) An investigator may be invited (telephonically/ through written communication) to the IEC meeting to discuss issues related to the study proposal.

g) An investigator may call up the IEC office to know the date of next scheduled meeting of the IEC.

h) For clinical study planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2006 guidelines.

i) An investigator may refer to the SOP on 'Exemption from the Ethics Review for Research Projects' - SOP no. 22 and 'Request for Waiver of Written Informed Consent' - SOP no. 23 whenever necessary.

j) An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable *AX 07/SOP 05/V1*

k) An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 180 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC office records.

II **Once approval for a study is granted**

a) An approval will be granted for the entire duration of the study.

b) It is the responsibility of the principle investigator that for studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval)

C) Submission of Study Related Documents for IEC review

Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review.

Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting and is sent to the IEC members at least 2 days in advance. Hence the study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received within seven days and other types of documents within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion (**Exception** - any matter which in the opinion of the IEC secretariat has direct bearing on the safety of the research participants such as SAE report, major protocol violation).

d) Submission of Amended Protocol and Protocol Related Documents

All amendments to the approved research proposal (only one set) should be submitted to the committee for its review no later than 7 seven days prior to the date of forthcoming meeting.

No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.

e) Submission of Report of Protocol Deviations/ Violations in the study protocol

Please use 1- Deviation / Non-Compliance / Violation Record AX 05/SOP 12/V1 for submitting report of Protocol Deviations / Non-Compliance / Violations.

f) Submission of Report of Serious Adverse Event (SAE)

The Principal Investigator should submit within 24 hours on the SAE report or the unexpected adverse event report as per the format specified in AX 05/SOP 14/V1 (Appendix XI of Schedule Y) and AX 02/SOP 14/V1 to the IEC or by email. The report of SAE of death after due analysis shall be forwarded by the investigator to chairman of the IEC and Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial is been conducted within 10 calendar days of SAE of death. The report of the SAE other than death after due analysis shall be forwarded by the investigator to Licensing Authority, chairman of the IEC and the head of the institution where the trial is been conducted within 10 calendar days of occurrence of SAE.

The SAE report should be accompanied by detailed narrative of the SAE and CDMS form.

It should be submitted as per checklist detailed by Licensing Authority in (Annexure A) and given in **AX** 01/SOP 14/V1.

The sponsor or his representative shall pay the compensation in case of clinical trial related injury or death within 30 days of the receipt of such an order from Licensing Authority.

g) Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

h) If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issued objections raised by the committee within twelve (12) weeks of the receipt of the committee's decision. In absence of appeal, the project will be declared closed in the IEC office records.

i) Submission of continuing review report in case of studies which continues for more than a year.

- For studies which will continue for more than a year, a continuing review report as per the format AX/02/SOP 10/V1 will need to be submitted for review
- If the Principal Investigator fails to submit the continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format AX/01/SOP 10/V1 within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

  a) A letter of reprimanding the Investigator

  b) Not reviewing future projects from the PI for a specified period of time

  c) A letter asking the Investigator to put recruitment of new participants on hold

III Once a study is over

Submission of Study Completion Report

For studies which are completed within the IEC approval period, a study completion report as per the format given in *AX 01/SOP 11/V1* should be submitted to the IEC, by the investigator. The study completion report is expected for review within 1 month of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from the sponsor.

IV In case a study is not initiated or terminated, the same should be communicated to the IEC stating reasons for the same. The format for submission of report of premature termination of the study is as per *AX 01/SOP 13/V1* should be used

1. The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same using the form1- Document Request Form *AX 01/SOP 19/V1*

   Sponsor responsibilities

   Any report of serious adverse event or death occurring in clinical trial after due analysis shall be forwarded by the sponsor to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.

   In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in SOP 5 Annexure 6.

Appendix I: Regulatory permissions

- **DCG(I) approval**

  Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DCG (I) permission. For such studies, a copy of the permission letter issued by the DCG (I) to the pharmaceutical company/investigator also needs to be submitted to the IEC. If the DCG (I) permission is awaited, a letter of provisional 'approval will be issued by the IEC and the final IEC approval will be given after a copy of DCG(I) permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.

- FDA marketing/manufacturing license for Ayurvedic/ herbal formulations/ nutraceutics
- Health Ministry Screening Committee (HMSC) approval in case a study involves collaboration with any foreign laboratory/clinic/institution
- Bhabha Atomic Research Centre (BARC) approval in case a study involves use of radioisotopes/ ionizing radiations

Submission of Projects for IEC Review

Submission of project proposal by Investigator [as per checklist –*AX 02/SOP 05/V1*]
(Sponsored by Pharmaceutical companies and Government Organizations)
[Till 20th of every month eg. 20th June]

↓

Documents checked by the Administrative officer

↓

Complete → Received by IEC → **1st Review**

Incomplete → Returned

Review by the IEC members by circulation of projects [about 4 weeks] and Discussion at full board meeting [3rd / 4th week of the next month eg. 3rd week of July]

↓

Decision communicated to investigator [within 14 days of meeting eg. 1st week of August]
(Approval/Disapproval with reasons/ Modifications in the proposal)

↓

Submission of response to IEC queries/modified project documents
[to be submitted within 180 days after the IEC query letter is sent]

↓

2nd Review

↓

Member Secretary/ Chairperson, informed to members at full board meeting

Full Board discussion

two/more designated members, informed to members at full board meeting

↓

Decision communicated to investigator [within 14 days of meeting eg. 1st week of August] (Approval/Disapproval with reasons/ Modifications in the proposal)

↓

3rd / Subsequent Review Procedures- Similar to 2nd Review

Annexure 6

AX 06/SOP 05/V1

Sample Format of an Informed consent document in English (This template should be customized according to the requirement of individual research project)

I Project title:

To test the efficacy and tolerability of XXXXXXXX (an antihypertensive test drug) as compared to XXXXX (a standard antihypertensive drug)

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from high blood pressure are at high risk for cardiovascular disease, including heart attacks, strokes and even death. Anti-hypertensive medications are commonly prescribed to such patients to prevent the occurrence of cardiovascular events. XXXX is a new drug, which has been found to decrease the blood pressure in initial studies. The study plans to study the efficacy and safety of this drug in patients having high blood pressure.

IV Expected duration of the study and number of research participants:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (If multicentric study – mention that the study is also being carried out at xxx other centers).

V Study procedures to be followed:

If you agree to participate in this study you will a)be asked about previous medical problems, your current health and your medications; b)have a brief physical examination (to give details);c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will be randomly assigned (like the flip of a coin) to a study group to receive one of the two study treatments.

The study would require a total of XX visits. At each visit XX ml (mention1-2 tsp/tbsp as applicable) of your blood will be withdrawn after fasting for XX hours. The blood samples that are drawn, will be used to check your blood sugar levels, kidney and liver function etc. (mention whatever is applicable).

Regardless of the group to which you have been assigned, you will return to the study centre after XXXX days / weeks / months. It is important that you bring all of your study medications, diary etc. along with you.

At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent heart attacks, strokes or death from cardiovascular causes:

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs proposed for use here are summarized below.

Side effects of test drug – XXXXX (Give Details)

Side effects of standard drug – XXXXX (Give Details)

Other side effects that you may experience could include injection site reactions, allergic reactions to the medication, itching rash and pain at the injection site (if the drug is to be administered parenterally). While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this form or any other ones to the study physician immediately at the numbers listed below.

Because the safety of the study drugs for an unborn fetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are no pregnant you will be asked to take precautions to prevent pregnancy until the end of the study. The doctors will discuss the contraception options with you. Pregnancy test may be repeated during the study. If you become pregnant despite these precautions you should immediately notify the study team. Pregnancy will be a reason to stop study treatment.

Any new important information that is discovered during the study and which may influence your decision to continue in the study will be provided to you or your legally acceptable representative in a timely manner. You will be told of any new risks or side effects.

VII Possible benefits of the study:

By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study your participation in this study may provide information that may in the future help other patients suffering from high blood pressure.

VIII What happens when the research trials stops?

Because this is a research trial, the test drug will not be available at the end of this trial for treatment of this disease. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the company sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. The medication and clinic visits will be provided free of charge. No compensation will be provided for your participation. Payment for things such as lost wages is not available. (Wherever applicable give details e.g. reasonable travel assistance will be provided for your participation etc.)

X Treatment and Compensation for study related injury:

You will be provided medical IEC at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical IEC will be at no cost to you. The study doctor/sponsor will compensate anyone in case there is temporary/ permanent disability or death as a direct result of participation in this trial In case of death, their dependents are entitled to material compensation.(provision of insurance coverage by the sponsor for study related injury, if available, may be stated here). You will not give up any of your legal rights by signing this form.

Any injury or death of the participant occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee (s) as the case can be are entitled for financial compensation .

a) adverse effect of investigational product (s)
b) violation of the approved protocol, scientific misconduct by the sponsor or the investigator.
c) failure of the investigational product to provide intended therapeutic effect
d) use of placebo
e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.
f) for injury to child in utero because of the parents participation in the trial
g) any clinical trial procedure involved in the study.

[Paragraph from ICMR 2006 guidelines –

Obligation of the sponsor to pay: The sponsor whether a pharmaceutical company, government, or an institution, should agree, before the research begins, in the a priori agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.]

[As per the notification from the office of DCGI (Notification GSR NO 53 (E) Dated 30-01-2016, 122 DAB), it is mandatory for the sponsors to comply the following requirement :

A. "In event of any injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
In the event of a trial related injury or death, the sponsor or his representative should

provide financial compensation for the injury or death. The financial compensation will be over and above any expenses incurred on the medical management of the subject.

In case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and same should be included in Patient Information Sheet / Informed Consent Form"].

B. Date of Birth /Age .....

Address of the subject.....

Qualification.....

Occupation- student/self-employed/service/housewife/other (please tick as appropriate)

Annual income of the subject .....

Name and address of the nominee(s) and his relation to the subject .....

(for the purpose of compensation in case of trial related death)

C. Name of the witness .....

(copy of the Patient information sheet and duly filled ICF shall be handed over to the participant or his/her attendant)

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study, you may have to undergo some tests and/or procedures, which will be done to protect your safety.

XII Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.

XIII Contact for further information:

Thank you for taking the time to read (or have read to you) the information about this study. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during & after the study.

If you have questions about this study or how it is being run, drug side effects or a possible research related illness or injury, you can contact the study doctor XXXXXXXX, designation, department XXXXXXXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.

If you have any questions about your rights as a research participant, or complaints regarding the research study, you should call XXXXXXX who is the Member Secretary of Institutional Ethics Committee on the following telephone number on working days. Tel.

no.: 91 22 2410 7000, Ext. 7515, 91 22 24107515, 91 22 24122188 (Monday to Friday- 9:00am to 4:00pm; Saturday-9:00am to 1:00pm).

XIV Consent:

[1] I have read or have had read to me the information given in the Informed Consent Document for this study entitled "XXXXXXX"

[2] I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.

[3] I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.

[4] I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

[5] Institutional Ethics Committee authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.

[6] I understand that my identity will not be revealed in any report or publication.

[7] I agree to take part in the above study.

Name of research participants	**Signature/ thumb impression of research participants**	**Date**

Name of Legal Representative (LAR)	**Relation to research participants**	**Signature / Thumb Impression of LAR**	**Date**

Name of the Impartial Witness	**Signature of the Impartial Witness**	**Date**

Name of the person Administering consent	**Signature of the person administering consent**	**Date**

Child assent statement for children above age 7 and below 18 (wherever applicable)

I have had the above research project explained to me in language that I can understand and I agree to participate.

Name of child	**Signature of child**	**Date**
Name of person obtaining Consent	**Signature of person obtaining consent**	**Date**

PLEASE NOTE THAT THE INFORMED CONSENT DOCUMENT SHOULD HAVE **PAGE NUMBERS**

Annexure 7

AX 07/SOP 05/V1

Format for Informed Consent Document for Genetic Studies

This document will, in general, follow the format of the informed consent document contained in Annexure 4 of SOP no. 5 *AX 04/SOP 05/V1*. The additional specific components related to genetic studies are elucidated here.

These guidelines are meant to provide assistance in framing informed consent documents for genetic research studies. The examples given may be inserted, where relevant, by the investigator/sponsor.

A. Project Title and Purpose of the Study

Given the more complex nature of genetic research, the sponsor/investigator should make the nature of the research abundantly clear to the research participant. The sponsor/investigator should also generally define genetic/genomic research in the context of the study under consideration in layman's terms. If the investigator so desires, a glossary of genetic terms used may also be provided.

Example:

1. *The purpose of this document is to enable you to understand the nature of the research that we are undertaking. Do take time to review this document IEC fully and do not hesitate to ask the investigator any question or clarification related to the research.*
2. *This study involves the analysis of how genes, blood components or DNA relate to the way that investigational therapies are absorbed, broken down and eliminated from the body, how they affect the body and how DNA relates to human disease."*

B. Study Procedures to be followed

The sponsor/investigator should explain in layman's terms the procedure to obtain any genetic material/tissue from a research participant.

C. Risks and Discomforts

The sponsor/investigator must explain the risks involved in the procedures to obtain any genetic material/tissue. Separate risks relating to genetic information obtained should also be explained.

Example: *"There is a chance that participation in this study could cause psychological distress, social and economic harm either to you individually or to your community."*

D. Possible benefits of the study

The sponsor/investigator ought to mention benefits if any that may accrue to the participants/community. If no such benefits are seen/ guaranteed at this point in time, the same may be explicitly stated. However, if there is a possibility of long-term societal benefits, this should be incorporated. The sponsor should also state his/her policy regarding commercial benefit to participant/community.

E. What happens when the research trial stops?

The storage of samples, the duration of such storage, the method of destruction of such samples should be stated. The possibility, if any, of using such samples in the future by the same or different investigators should be mentioned. Also, if the genetic study is being carried out as a sub-study, it ought to be stated that stoppage of the genetic study would not result in automatic cessation of the main study. If the study is stopped before schedule and the data is not anonymised, the option of knowing the results of the study should be made available to the research participant. Moreover, if the results of the study indicate that there might be implications for the participant, as regards future medical conditions; appropriate counseling ought to be provided. For example, the necessity of avoiding certain drugs in the future should be explained.

The genetic studies are often carried out as part of basic research and the data generated in initial studies is inadequate. It may inappropriate to use the preliminary data in management of patient's condition. This aspect needs to be explained (whenever applicable).

Example: *These analyses are done as part of basic research. Basic research analyses are performed under conditions that are different from routine laboratory testing that your doctor may do. Therefore, it would not generally be appropriate for your doctor to use these results as part of your IEC."*

F. Compensation for participation and Treatment and Compensation for study related injury

The provisions of the earlier format contained in Annexure 4 of SOP no. 5 (*AX 04/SOP 05/V1*) are applicable.

G. Right to withdraw from the study

If the genetic study is being carried on as a sub-study, withdrawal from the genetic study should not affect participation in the main study. The participant should be given the right

to request for destruction of his/her sample provided the sample has not been anonymised till that time.

H. Confidentiality

The participant should be informed whether the samples are to be unidentified, unlinked or coded as defined in the ICMR Guidelines, 2006. If the investigator does not intend to disclose the results of the study (for example, in the case of a preliminary/pilot study), the samples should be 'anonymous.'

If the investigator intends to disclose the results of the genetic testing, the participant should have the right to decide whether or not he desires such disclosure. Family members are not entitled to know each others' diagnosis and specific consent is needed from a participant before sharing the information with family members.

Example: *The investigator will provide the genetic analyses to your family, the doctor conducting the main study or any doctor involved in your IEC, your insurance company or your employer, only after obtaining your written consent. However, this is subject to the requirement of disclosure of such information to a court of law. It may also be made accessible to members of the IEC and regulators."*

Title: Initial Review of Submitted Protocol

SOP Code: SOP 06/V1 dated 22nd August 2016

Authors:

Dr. Rahul Prakash Bhavasar, (Member, IEC) 01.09.2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	3
6	Glossary	7
7	References	8
8	Annexure	9

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) members will review an initially submitted protocol for approval using the Assessment Form for initial review. The Assessment Form *AX 02/SOP 06/V1* is designed to standardize the review process and to facilitate reporting, recommendations and comments given to each individual protocol.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from the IEC. The specific points in the guidelines attached to the Assessment Form for initial review must be adequately addressed in the protocol itself and/or protocol-related documents under review. Relevant queries/comments made during discussion and deliberation about a specific protocol should be recorded in the minutes of the meeting.

The decision reached by the IEC and the reasons for its decision is recorded on the IEC Decision Form *AX 03/SOP 06/V1*.

3. Responsibility

It is the responsibility of all the IEC members to fill the Assessment form along with decision and comments they might have after reviewing each study protocol. The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chairperson must sign and date to approve the decision in the IEC Decision Form *AX 02/SOP 06/V1*.

4. Flow chart

No.	Activity	Responsibility
1	Summarize the protocol in an Assessment Form and distribute the protocol package	Secretariat
2	Receive the distributed protocol Package	IEC members
3	Verify the contents of the package	IEC members
4	Review the Protocol	IEC members
5	Examine the qualification of investigators and of study sites	IEC members
6	Review study participation	IEC members
7	Examine community involvement and impact	IEC members
8	Make a decision	IEC members
9	Gather the assessment reports	Secretariat
10	At the IEC meeting record the IEC Decision	Secretariat

11	Final communication of the IEC Decision taken on the project to the Principal Investigator	Secretariat
12	Storage of documents	Secretariat

5. Detailed instructions

5.1 Distribute the protocol package.

The Secretariat will fill in the required details in the letter to the IEC Members requesting initial review *AX 01/SOP 06/V1* and the study assessment form *AX 02/SOP 06/V1* prior to circulation to the IEC members. The Secretariat will attach the letter to IEC Members requesting Initial Review with study assessment form *AX 01/SOP 06/V1* with the Project Submission Application Form *AX 01/SOP 05/V1*, Document Checklist *AX 02/SOP 05/V1*, the protocol and related documents and send the packet to the IEC members. The Study Assessment Form for Initial Review *AX 01/SOP 06/V1* will be included along with the letter to IEC Members requesting Initial Review with study assessment form *AX 01/SOP 06/V1*, the Project Submission Application Form -*AX 01/SOP 05/V1*, Document Checklist *AX 02/SOP 05/V1*, the protocol and related documents and will be sent to the respective primary reviewers.

5.2 Receive the distributed protocol Package:

The IEC member will receive the protocol package with the Project Application Form *AX 01/SOP 05/V1*, Checklist of all documents *AX 02/SOP 05/V1*. The primary reviewers will also receive the Study Assessment Form for Initial Review *AX 01/SOP 06/V1*

5.3 Verify the contents of the package

- The IEC member will verify all the contents.
- The IEC member will check the meeting date to see if it is convenient to attend the meeting.
- The IEC member will notify the IEC Secretariat if there are documents missing in accordance to *AX 02/SOP 05/V1* or if the specified date of the IEC meeting is not convenient to attend.

5.4 Appointment of primary reviewers

- The Member Secretary/Chairperson will appoint one or more primary reviewers for each project on the basis of expertise in the related field and experience. The primary reviewer(s) will make his/her comments and fill the study assessment form *AX 02/SOP 06/V1*. They will present the summary of the project and the comments at the IEC board meeting.

5.5 Review by the IEC members

5.5.1 Review of the protocol

- The protocol will be reviewed by each member as per guidelines to review a study protocol described in *AX 05/SOP 06/V1*.

- The IEC member will consider the following criteria when performing the review of the study protocol:
  - ✓ minimize risks to participants;
  - ✓ risks must be reasonable in relation to anticipated benefits;
  - ✓ participants are selected equitably;
  - ✓ informed consent is adequate, easy to understand and properly documented;
  - ✓ the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - ✓ there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
  - ✓ Appropriate safeguards are included to protect vulnerable participants.

5.5.2 Examine the qualification of investigators and assess adequacy of study sites

The IEC members must consider whether the qualifications of the participating investigators relate to the study by reviewing their CVs.

- The IEC members must examine disclosure or declaration of potential conflicts of interest
- The IEC members must assess / ascertain, if required by reviewing the study site whether the facilities and infrastructure at study sites can accommodate the study.

5.5.3 Review study participation

The IEC member will examine for the presence of the following points while reviewing the patient information sheet/Informed Consent Form as per guidelines to review protocol and Informed Consent Document/Patient Information Sheet in *AX 05/SOP 06/V1*.

- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society

- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: Reasonable
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

5.5.4 Examine community involvement and impact

The IEC members will also consider the following points in the protocol, Informed Consent Form/ Patient Information Sheet

- Community consultation
- Benefit to local communities
- Contribution to development of local capacity for research and treatment
- Availability of study results

5.6 Provisional decision by the IEC members.

- The IEC members will write comments and suggestions after complete review of protocol and related documents in the space provided in Annexure 1 *AX 01/SOP 06/V1*. The IEC members will record the provisional decision by marking in the desired block on any of the following: *"Approved, Suggested recommendations, to be discussed at IEC meeting, Disapproved(with reasons) or Any other*

5.7 Gather the assessment reports.

The IEC Secretariat will collect the Assessment Forms *AX 01/SOP 06/V1*, the comments from each reviewer and file in the original set of the study file.

5.8 At the IEC meeting

During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form. The comments of an independent consultant (if applicable) will be discussed by the member secretary. The other IEC members shall give their comments right after the presentation.

- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.
- The IEC members will discuss and clarify the comments and suggestions. The Member secretary (assisted by the Secretarial staff) shall record the discussions
- The final decision on the project as: "Approved/ Disapproved/ Suggested recommendations or any other----" in the meeting shall be by voting and will be recorded in the IEC Decision Form *AX 03/SOP 06/V1 by the Member Secretary*.

- A majority vote for approval, disapproval, request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
- An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of the committee.
- Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.

- If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the IEC decision is 'Suggested recommendations', it implies that the items noted at the convened meeting require modifications and project should be re-submitted to the IEC.
- If the changes requested are of minor nature, the IEC Chairperson may authorize the Secretary to determine if the response and changes are satisfactory and decide if letter of permission can be issued to the Principal Investigator.
- The Chairperson may send the response and amended protocol/ documents to one or more IEC members to recommend if letter of permission can be issued after satisfying himself/ herself/ themselves about satisfactoriness of the response and changes
- The response and changes carried out may be considered for discussion at a future IEC meeting.
- If the IEC decision is 'Disapproved' or any other, the decision should be made on the basis of specific reasons which are communicated by the IEC to the principal investigator in the letter of notification.

  The Secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the IEC Decision Form *AX 03/SOP 06/V1*.
- If the study is approved, the Committee will determine the frequency of Continuing Review from each investigator.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.
- With the study protocol, the Assessment Form from all members and IEC Decision Form will be filed in the project file by the Administrative Officer.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

5.9 Final communication of the IEC decision taken on the project to the Principal Investigator

- The Secretariat will prepare an approval letter as *AX 04/SOP 06/V1* to be sent to the Principal Investigator when the project is approved at an IEC meeting.
- The letter contains, at a minimum:
  - Project reference number
  - Project title
  - A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - The approval is provided for the entire duration of the project.
  - List of IEC members present at the meeting when the project was approved.
  - The Chairperson / Member Secretary will sign the approval letter and the Secretariat will send it to the Principal Investigator within 14 days
- If the Committee disapproves a study, the Secretariat immediately notifies the investigator in writing about the decision and the reason/s for not approving the study within 7 working days. A notifying letter to the investigator should state the following:

  "If you wish to appeal to this decision, please contact the IEC and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the IEC Chairperson with justification as to why the appeal should be granted. In absence of appeal, the project will be declared closed for the IEC office records."

  If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IEC. The Principal Investigator will be asked to respond to the letter of comments/queries within 180 days of the receipt of the letter by the investigator. In the absence of any response, the project will be declared closed for the IEC office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.

5.10 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the project file along with all the reviewed documents.
- The Administrative Officer will store the file on an appropriate shelf in the designated cabinet.

6. Glossary

Study Assessment Form	An official record that documents the protocol review process.

Document	Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Pre-clinical study	Animal and *in vitro* studies provide information on possible toxicities and mechanisms of action, and starting doses for human studies.
Vulnerable research participants	A vulnerable category of research participants includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
Initial Review	The first time review of that protocol made by two or three individual reviewers (IEC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Phase I studies	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016).

[3] Cavazos N., Forster D., and Bowen A.J., Ethical Concerns in Placebo-controlled studies: An Analytical Approach, Drug Information Journal 36(2) 2002: pgs 249-259, via WIEC documents

8. Annexure

Annexure 1	*AX 01/SOP 06/V1-*	Letter to the IEC Members requesting Initial review with study assessment form
Annexure 2	*AX 02/SOP 06/V1-*	Study Assessment Form
Annexure 3	*AX 03/SOP 06/V1-*	IEC Decision Form
Annexure 4	*AX 04/SOP 06/V1 -*	Format of Project Approval letter
Annexure 5	*AX 05/SOP 06/V1 -*	Guidelines for reviewing a study protocol

Annexure 1

AX 01/SOP 06/V1

Letter to IEC Members requesting Initial Review with study assessment form

Dear member,

The next meeting of the IEC will be held on XXX at XXX in XXXX.

Please note that the package of research proposals is to be circulated in the following order. You are requested to review the same preferably within 5 working days of receiving the package. Please review the protocol and related documents as per the guidelines attached with Annex 1 and provide your comments below and fill the study assessment form (for primary reviewers only) provided with the package (*AX 02/SOP 06/V1*). Please also confirm your availability for the meeting.

Name of Member	Date of Receipt	Signature	Attending meeting Y/N

Protocol Number : (as per IEC records)	Date of receipt at IEC office after review by member (D/M/Y):
Protocol Title :	

4a	What should be improved? Background Information and Data ☐ sufficient ☐ insufficient	Comment:
4b	Risks and Benefits Assessment ☐ acceptable ☐ unacceptable	
4c	Inclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
4d	Exclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
4e	Discontinuation and Withdrawal Criteria ☐ appropriate ☐ inappropriate	Comment:
5	Involvement of Vulnerable Participants: ☐ Yes ☐ No	Comment:
6	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	Comment:
7	Sufficient number of participants? ☐ Yes ☐ No	Comment:
8	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:
9	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
10	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
11	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	Comment:
12	Community Consultation: ☐ Yes ☐ No ☐ NA	Comment:
13	Benefit to Local Communities ☐ Yes ☐ No	Comment:
14	Contribution to development of local capacity for research and	Comment:

Name of the Principal Investigator	Designation	Department
Name of the Reviewer:		

Comments:

Signature of IEC member reviewing the project:		**Date:**

Annexure 2

AX 02/SOP 06/V1

Study Assessment Form to be used by the Primary Reviewer

IEC Protocol Number :		Date (D/M/Y):	
Protocol Title			
Principal Investigator:			
Department			
No. of Participants at the site:		No. of Study site(s):	

Mark and comment on whatever items applicable to the study.

1	Objectives of the Study ☐ clear ☐ unclear	What should be improved?
2	Need for Human Participants ☐ Yes ☐ No	Comment:
3	Methodology: ☐ clear ☐ unclear	

	treatment ☐ Yes ☐ No	
15	Availability of similar Study / Results: ☐ Yes ☐ No	Comment:
16	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	Comment:
17	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
18	Contents of the Informed Consent Document: ☐ clear ☐ unclear	Comment:
19	Language of the Informed Consent Document: ☐ clear ☐ unclear	Comment:
20	Contact Persons for Participants ☐ Yes ☐ No	Comment:
21	Privacy & Confidentiality ☐ Yes ☐ No	Comment:
22	Inducement for Participation ☐ Unlikely ☐ Likely	Comment:
23	Provision for Compensation for Participation ☐ appropriate ☐ inappropriate	Comment:
24	Provision for Treatment for Study-Related Injuries ☐ appropriate ☐ inappropriate	Comment:
25	Provision for Compensation for Study Related Injuries ☐ appropriate ☐ inappropriate	Comment:

Reviewer's Signature with date: _____

Annexure 3

AX 03/SOP 06/V1

IEC Decision Form

Date of IEC meeting: _____

Protocol number: _____

IEC Protocol No. and Title:	
Principal Investigator:	Department:
Final Decision at the meeting:	☐ Approved ☐ Approved with modifications ☐ Resubmission ☐ Disapproved ☐ Reviewed at the Full Board meeting ☐ Review by any 2 / more IEC members ☐ Monitoring required Reason:_____ **Disapproved, Reasons:** _____ _____

No.	Names of Members present	AP	AM	RS	DA	Signature

Note: *AP: Approved; AM: Approved with modification [(either primary reviewer/full board) if reviewed by full board again a decision form has to be filled; RS: Resubmission; DA: Disapproved.*

Comments:

No. of members voting for the decision:

No. of members voting against the decision:

No. of members abstaining from voting:

_____

Signature of Chairperson **Date:** _____

Annexure 4

AX 04/SOP 06/V1

Format of Interventional Project Approval letter

Date XX/XX/XXXX

To,

Dr. xxxxxxxxxxx,

Dept. of xxxxxxxxxxxx.

Ref: The project no. EC/xxx/20xx entitled, "xxxxxxxxx".

Sub: Letter no.

Dear Dr. XXXXx,

The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxxxxxxxxx with xxxxx as Chairperson.

xxxx members attended the meeting held on xxxx. The list of members who attended the meeting is as follows.

Name of Members	Position on IEC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at Dept. of xxxx, Seth DR. Ulhas Patil Medical College and Hospital as per the submitted protocol.

This approval is valid for the entire duration of the study.

It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP 14/V1 (Appendix XI of Schedule Y) and AX 02/SOP 14/V1 to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to chairman of the IEC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death.

The sponsor has to forward the report of SAE or death after due analysis to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in SOP 5 Annexure 6.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before XXXXXXXXXX.

A copy of the final report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairperson,
IEC
(Signed and dated by the IEC Chairperson or Member Secretary)

Date of approval of the study: XX/XX/20XX

Annexure 5

AX 05/SOP 06/V1

Format of Observational Project Approval letter

Date XX/XX/XXXX

To,

Dr. xxxxxxxxxxx,

Dept. of xxxxxxxxxxxx.

Ref: The project no. EC/xxx/20xx entitled, "xxxxxxxxx".

Sub: Letter no.

Dear Dr. XXXXx,

The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxxxxxxxxx with xxxxx as Chairperson.

xxxx members attended the meeting held on xxxx. The list of members who attended the meeting is as follows.

Name of Members	Position on IEC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC has reviewed and approved the following documents submitted for the above – mentioned clinical study.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at Dept. of xxxx, Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

This approval is valid for the entire duration of the study.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to

eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before XXXXXXXXXX.

A copy of the final report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairperson,
IEC
(Signed and dated by the IEC Chairperson or Member Secretary)

Date of approval of the study: XX/XX/20XX

Annexure 6

AX 06/SOP 06/V1

Guidelines for reviewing a study protocol

Reviewers should think about and try to find answers to the following questions:

1. How will the knowledge, result or outcome of the study contribute to human well-being?
   - ❑ Knowledge from the basic research may possibly benefit.
   - ❑ A new choice of method, drug or device that benefits the research participants during the study and others in the future.
   - ❑ Provide safety data or more competitive choices.
2. Does the study design will be able to give answers to the objectives? Whether
   - ❑ The endpoints are appropriately selected.
   - ❑ The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - ❑ The control arm is appropriately selected for best comparison.
   - ❑ The placebo is justified.
   - ❑ The number of study participants in non-treatment (or placebo) arm is minimized.
   - ❑ Unbiased assignment (e.g. randomization, etc.) is in practice.
   - ❑ Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as much as possible.
   - ❑ The sample group size appropriate with the given statistical assumptions.

- Predictable risks are minimized.
- The tests and procedures that are more than minimal risk are cautiously used.
- Research participants deception is avoid.
- Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
- The study participants are adequately assessed and provided follow-up care, if needed.

3. Who will be the participants in the study? Whether
   - The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.
   - It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
   - There will be secondary participants.
4. Do the inclusion and exclusion criteria
   - Selectively include participants most likely to serve the objective of the study?
   - Equitably include participants?
   - Properly exclude participants who can predictably confound the results?
   - Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances?
5. Does the study design have adequate built-in safeguards for risks?
   - Appropriate screening of potential participants?
   - Use of a stepwise dose escalation with analysis of the results before proceeding?
   - Does the frequency of visits and biological samplings reasonably monitor the expected effects?
   - Are there defined stopping (discontinuation) / withdrawal criteria for participants with worsening condition?
   - Is there minimized use of medication withdrawal and placebo whenever possible?
   - Will rescue medications and procedures be allowed when appropriate?
   - Is there a defined safety committee to perform interim assessments, when appropriate?
   - Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and *in vitro* testing results?
   - Previous clinical results, if done?

- Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
  - The selected dose based on adequate prior results?
  - Monitoring tests designed to detect expected possible risks and side effects?

7. Do the study and the informed consent process include issues of special concern, such as:
   - Waiver or alteration of consent?
   - Delayed consent (e.g., emergency treatment, etc.)?
   - Deception?
   - Sensitive information of participants that may require a confidentiality statement?

Guidelines to review Informed Consent Document/Patient Information Sheet The actual process of informed consent should:

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.
- Make sure that all information is understood and satisfied by the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.
- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be informally verified on a continuing basis.
- Continue to inform the participants throughout the study.
- Continue to re-affirm the consent to participate throughout the study.

Procedures or methods used in the informed consent process if recruitment of study participants include:

- A consent form
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)
- Internet information
- Instruction sheets
- Audio-visual presentations
- Charts, diagrams or posters
- Discussions

1) Is the risk of using placebo instead of treatment life threatening?

   If yes, placebo is not acceptable.

2) Is the use of placebo instead of treatment likely to lead to permanent damage?

   If yes, placebo is not acceptable.

3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

   If yes, placebo is not acceptable.

4) Can the use of placebo instead of treatment lead to an acute emergency?

5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?

6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

   If answers of (4) *to* (6) *are "yes", placebo is not acceptable unless risk management is adequate.*

III. Risk management

1) Is there benefit in the overall management of the research participants?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended.*

2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

   ☐ *No, consider placebo*

   ☐ *Yes, placebo not recommended.*

3) Are research participants at high risk for the use of placebo excluded?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended.*

4) Is the duration of the study the minimum necessary in relation to the action of the drug?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended.*

5) Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended.*

6) Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?

   ☐ *Not applicable.*

- Consultation with others

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words; remove technical jargon and medical terms.
- Try to use correct basic grammar and form.
- Use "gene transfer" instead of "gene therapy" (less implied effectiveness).
- Use "agent" instead of "drug" or "medicine" (less implied effectiveness).
- Try to avoid the use of "treatment", "therapy" or "therapeutic" in studies involving gene transfer (because these words imply effectiveness)

Guidelines to Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease Board decision.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

If the answers of (1) to (6) are "yes", placebo is not recommended. If any one or more answers are "no", placebo may be possible.

7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?
9) Does standard treatment have contraindications that prevent some research participants from being treated?
10) Is there substantial (≤25%) placebo response in this disease or symptom? *If the answer of* (7) *to* (10) *are "no", placebo is not recommended.*

If any one or more answers are "yes", placebo may be possible.

II. Risks of placebo

☐ *Yes, consider placebo*

☐ *No, placebo not recommended.*

7) Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression?

☐ *Yes, consider placebo*

☐ *No, placebo not recommended.*

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

☐ *Not applicable.*

☐ *Yes, consider placebo*

☐ *No, placebo not recommended.*

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

☐ *Not applicable.*

☐ *Yes, consider placebo.*

☐ *No, placebo not recommended.*

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

☐ *Not applicable.*

☐ *Yes, consider placebo.*

☐ *No, placebo not recommended.*

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?

☐ *Yes, consider placebo.*

2) Are the risks of the test drug disclosed?

☐ *Yes, consider placebo.*

3) Are the advantages of alternative treatments explained?

☐ *Yes, consider placebo.*

Conclusions:

1. The use of placebo is ethically acceptable because:

   ☐ Research participants are not exposed to severe or permanent harm by the use of placebo.

   ☐ Research participants under placebo will benefit from the overall treatment of the disease.

   ☐ Risks of the use of placebo are minimized.

   ☐ Risks are adequately disclosed in the consent form.

Title: Expedited Review

SOP Code: SOP 07/V1 dated 22nd August 2016

Authors:

Dr.Rahul Prakash Bhavasar, (Member, IEC) 01.09.2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date) 01/09/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	3
7	References	4
8	Annexure	4

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide criteria to determine if a study protocol qualifies for expedited review and provide instructions on management, review and approval of a project through the expedited review.

2. Scope

This SOP applies to the initial review and approval of study proposals with 'not more than minimum risk' to participants.

3. Responsibility

It is the responsibility of the Chairperson of the Institutional Review Board (IEC) to determine if a Project/ Protocol qualifies for an expedited review.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the submitted documents	Secretariat
2.	Determine protocols for expedited review	IEC Secretary
3.	Approve the Secretary's recommendation regarding the protocols for expedited review	Chairperson
4.	Expedited process	IEC Members/Chairperson
5.	Decision of IEC	Chairperson
6.	Communicate with the IEC and the Investigator	IEC Secretariat/ Members

5. Detailed instructions

5.1 Check and receive the submitted documents.

- The Secretariat will check and receive documents as described in 5.1 and 5.2 of SOP 5.

5.2 Determine protocols for expedited review.

The proposal submitted for initial review satisfying any of the following criteria (as per ICMR 2006 guidelines) may be considered for expedited review. The IEC Chairperson will take the final decision regarding whether a study with 'not more than minimal risk' qualifies for an expedited review.

- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
- Research on interventions in emergency situations.
- Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include

collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.

- Clinical studies of drugs and medical devices only when

  i. research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or

  ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

- Research on Disaster management.

5.3 Expedited Process

- After determining that the Protocol / Project qualifies for an expedited review, the Chairperson will nominate two or more IEC members to review the amended protocol. The Form *AX 01/SOP 07/V1* will be used by the Chairperson to nominate members.
- The comments of the IEC members will be recorded on *AX 02/SOP 07/V1*.

  The comments of the members will be discussed by the Member Secretary with the Chairperson and decision about approval will be taken by the Chairperson. The final decision by the Chairperson will be recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 07/V1*.
- The decision will be informed to the IEC members at the full board meeting.
- If deemed necessary by reviewer(s), Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting. The final decision by the Chairperson is recorded on the Study Assessment Form for Expedited Review *AX 02/SOP 07/V1*.
- The expedited review process should be completed within 14 working days.

5.4 Communicate with the IEC and the investigator.

- The Secretary will inform the IEC members of the proposals approved by expedited review at its regular meetings. The Secretariat will send the Project approval letter to the Principal Investigator, if the Project/ Protocol amendment are approved.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator in writing. The reasons for disapproval of a project will be specified in the letter sent to Principal Investigator.

6. Glossary

	Expedited An IEC approval granted only by the Chairman of the Institutional Review **approval** Board or a designated Institutional Review Board member (not the full Board) for research which involves no more
	than minimal risk. **Expedited** A review process by only two designated IEC members who then report the

review	decision to the full Board meeting. An expedited review is a *speedy* one for *research proposal* with *minimal risk in nature*.
Expedited meeting	A meeting that will exclusively concern only those projects, which are subjected to expedited review and will be attended by the Chairperson, Secretary/Associate Member Secretary and 2 Institutional Review Board members designated to perform the expedited review. This expedited meeting will be conducted as per SOP 16/V1.

7. References

[1] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

[3] WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

8. Annexure

Annexure 1	*AX 01/SOP 07/V1*	Form for nomination of IEC members for Review
Annexure 2	*AX 02/SOP 07/V1*	Study Assessment Form for Expedited Review

Annexure 1

AX 01/SOP 07/V1

Form for nomination of IEC Members for Review

Date: XXXX

To,
XXXXXXx,
Member, IEC,

Ref: The project no. **EC/PHARMA-XX/200X** entitled, "XXXXXXXX".

Sub: Review of XXXXXXX.

Dear Dr. XXXXXX,

The following document/s has/ have been submitted to the IEC for review.

1. _____
2. _____
3. _____

The following members are nominated to review/ carry out an expedited review of the above-mentioned documents.

1. _____
2. _____
3. _____

For expedited review, you are requested to fill the study assessment form enclosed (Annexure *AX 02/SOP 07/V1*) and send to the IEC office within 7 working days:

_____

Signature of Chairperson with date

Annexure 2

AX 02/SOP 07/V1

Study Assessment Form for Expedited Review

IEC Protocol Number :	Date of receipt at IEC office (D/M/Y):	
Project Title : _____		
Name of the Principal Investigator	Department	Telephone number (Office and / or mobile)
Total no. of Participants at the site:		
No. of Study sites:		
Sponsor:		
Duration of the Study:		
Reviewer's name :		
Type of the Study :	☐ Intervention ☐ Epidemiology ☐ Observation ☐ Document based ☐ Genetic ☐ Social Survey ☐ Others, specify.....	

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized	☐ Open-labelled	
☐ Double blinded	☐ Placebo controlled	☐ Treatment controlled
☐ Cross-over	☐ Parallel	☐ Interim Analysis
☐ Use of Tissue samples	☐ Use of Blood samples	☐ Use of genetic materials

Comments:

(Review the protocol and related documents as per the guidelines stated in *AX 05/SOP 06/V1)*

Provisional Decision: ☐ Approved ☐ Resubmission ☐ Disapproved ☐ Full Board ☐ Approved with modifications

Reason for disapproval _____

Name of the IEC member _____

Signature _____ **Date** _____

Final Decision:

Approved YES ☐ NO ☐

If disapproved, reasons for disapproval _____

Further revision or modification required/resubmission ☐

Any Other ☐ _____

Signature of the Chairperson: _____ Date: _____

Annexure 3

AX 03/SOP 07/V1

Approval letter format in case of Expedited Review

Date: xxxxxxxxx

To,
Dr. xxxxxxxxxxxxx,
Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through an expedite process.

1xxx
2.xxxxxxx
3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at Dept. of xxxxxxxxx, DR. Ulhas Patil Medical College and Hospital, JALGAON as per the submitted protocol.

The IEC approves the above mentioned study.
This approval is valid for the entire duration of the study.

It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP 14/V1 (Appendix XI of Schedule Y) and AX 02/SOP 14/V1 to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to chairman of the IEC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death.

The sponsor has to forward the report of SAE or death after due analysis to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in SOP 5 Annexure 6.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx.

A copy of the final report should be submitted to the IEC for review.

Sincerely yours

xxxxxxxxxx
Chairperson

Date of approval of the study: xxxxxx

Title: Review of Resubmitted Protocols

SOP Code: SOP 08/V1 dated 22nd August 2016

Authors:

Dr. Rahul Prakash Bhavasar, (Member, IEC) 01.09.2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2

5	Detailed Instructions	3
6	Glossary	5
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Institutional Ethics Committee (IEC) manages resubmitted study protocols.

2. Scope

This SOP applies to study protocols that have been resubmitted to the IEC with the Principal Investigator responding to clarifications and modifications sought and comments made by the IEC during initial review.

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC for reconsideration of a protocol; which is previously reviewed earlier with recommendations from IEC for some changes.

A re-submitted protocol may be reviewed by either the Chairperson or two or more IEC members designated by the Chairperson/ Member secretary, or all the IEC members as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting. This information can be found on the IEC Decision Form (*AX 03/SOP 06/V1*).

4. Flow chart

No.	Activity	Responsibility
1	Receive resubmitted protocol package, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents	IEC Secretariat
2	Review the revised protocol	IEC Members/Member Secretary/ Chairperson
3	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed instructions

5.1 Receipt of resubmitted protocol package and its distribution

- The Secretariat will verify if the principal investigator has forwarded the reply within 180 days of receipt of the letter of comments by the IEC.
- The Secretariat will check the resubmitted protocol packages (hard and soft copy) for the following items
  - ✓ Reply to the IEC letter of comments
  - ✓ Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc are included as part of the package with the changes made to the documents either underlined or highlighted.
  - ✓ Additional documents sought during initial review
- If above items are not submitted the Principal Investigator will be told to submit the complete package along with all the required documents.
- The Secretariat will refer to the IEC Decision Form *AX 03/SOP 06/V1* on the given protocol and distribute this package containing the reply to the query letter, revised protocol and related documents along with Assessment Form for resubmitted protocol to
  - ➢ The Member Secretary for summarizing and including it on the agenda for full board discussion in the forthcoming meeting if the decision on the protocol was 'to be discussed at full board'
  - ➢ The designated IEC members if the decision on the protocol was 'to be reviewed by two or more IEC members'. The selection of the two or more IEC members is done by the Chairperson at the time of initial full board review or later.
  - ➢ The Chairperson/Member Secretary if the decision on the protocol was 'Approved with recommendations subjected to review by Chairperson/Member Secretary only' as per IEC Decision Form *AX 03/SOP 06/V1*.

5.2 Review the revised protocol to be carried out by IEC member/ Member Secretary/ Chairperson:

- The IEC member/ Member Secretary/ Chairperson will refer to the query letter/ comments as guidance for the review and consider whether the recommendations of the IEC have been followed or adequately responded to.
- The IEC member/ Member Secretary/ Chairperson will make further comments where appropriate, in the Assessment Form for resubmitted protocol *AX 01/SOP 08/V1*

- The Secretariat will retrieve the Assessment Form for resubmitted protocol *AX 01/SOP 08/V1* from the members/Member Secretary/Chairperson.
- In case the decision is to discuss the revised protocol at the full board meeting, the Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.
- The Chairperson shall entertain discussion on the protocol revision from all the IEC members.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
  a) Approved
  b) Modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC members after receipt of the requested modifications:
  c) Disapproved giving reasons for disapproval
- In case the revised protocol is already approved by the chairperson, the decision is informed to the members at the full board meeting.

5.3 Review of the revised protocol to be carried out at IEC meeting

- The Secretariat shall receive the Assessment Form for resubmitted protocol *AX 01/SOP 08/V1* from the members/Member Secretary/Chairperson.
- The Secretary shall present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.
- The final decision regarding the research project shall be reached by voting (2/3rd majority of the members present and voting) and shall include one of the following:
  a) Approved
  b) Require modifications to items noted at the convened meeting and follow-up by the Chairperson/ Member Secretary /IEC *members* after receipt of the requested modifications: *Approved with modification*
  c) Resubmission
  d) Disapproved giving reasons for disapproval

5.4 Recording of the decision

- This IEC decision will be recorded by the Secretariat in the IEC Decision Form *AX 03/SOP 06/V1*.

5.5 Written communication of the IEC decision.

- The Administrative Officer will place the original completed documents along with the completed Form *AX 01/SOP 08/V1*, the Assessment Form and the Initial Review Application Form *AX 01/SOP 06/V1* as well as the others in the protocol package.

  The Secretariat shall then prepare a letter addressed to the investigator notifying the IEC decision (approval/ disapproval with reasons/ letter of comments) and shall take the Member Secretary or Chairperson's signature on it. The letter of comments sent to the investigator shall state that the reply to the letter is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records.

6. Glossary

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.
Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

8. Annexure

ANNEXURE 1 *AX 01/SOP 08/V1* Assessment of Resubmitted Protocol

Annexure 1

AX 01/SOP 08/V1

Assessment of Resubmitted Protocol

Protocol Number Protocol Title:	
Number of review : ☐ 2nd Review ☐ 3rd Review ☐ 4th Review _____	
Principal Investigator:	Department:
Date of Initial Review by IEC:	Date of Last Review:
The IEC Decision recorded in the meeting minutes : (meeting held on _____)	
Opinion of the reviewer:	
Revision or Modification according to the recommendation	☐ Yes ☐ No: Explain: _____
Approved	☐ Yes ☐ No
If disapproved, reasons for disapproval	_____
Further revision or modification required	_____
To be discussed at the forthcoming full board meeting	_____
Any Other	_____
Name of the Reviewer: 1) _____ **Signature:** _____ Date: _____ **Name of the Reviewer: 2)** _____ **Signature:** _____ Date: _____	
Final Decision: Approved YES ☐ NO ☐ If disapproved, reasons for disapproval _____ Further revision or modification required/ Resubmission ☐ Any Other ☐ **Signature of the Member Secretary/ Chairperson:** _____ Date: _____	

Title: Review of Amended protocol/ Protocol related documents

SOP Code: SOP 09/V1 dated 22nd August 2016

Authors:

Dr. Milind Joshi, (Member, IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson,
IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	5
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how amended protocol/ protocol related documents are managed and reviewed by the Institutional Review Board (IEC).

2. Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols will not be implemented until reviewed and approved by the IEC.

3. Responsibility

It is the responsibility of the IEC Secretariat to manage protocol amendments. The Member Secretary/ Chairperson will decide whether the proposed protocol amendment(s) need to undergo a full board review, review by designated IEC members or a review by the Member Secretary/Chairperson. The Member Secretary / Chairperson can take the decision if the amendment(s) is / are of administrative nature.

4. Flow chart

No.	Activity	Responsibility
1.	Receive the Amendment Package and Verify the contents	IEC Secretariat
2.	Notify the Member Secretary/Chairperson of the IEC	IEC Secretariat
3.	Determine whether full board review/ review by designated members is needed	IEC Member Secretary / Chairperson
4.	Nomination of Members for review	IEC Chairperson
5.	Distribution to IEC members	IEC Secretariat
6.	Protocol Amendment Review Process	IEC Members / Member Secretary /Chairperson
7.	IEC Decision	IEC Member Secretary / Chairperson
8.	Communication of the Decision to the Principal Investigator	IEC Secretariat
9.	Store documents	IEC Secretariat

5. Detailed instructions

5.1 Receiving the Amendment Package and Verification of the contents

- The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the Secretariat.

The Secretariat will confirm the request related documents from the Principal Protocol/Protocol related documents as per

- The request form should:
  - ✓ state/describe the amendment
  - ✓ provide the reason for the amendment
  - ✓ state any untoward effects with original
  - ✓ state expected untoward effects, if any
- The Administrative Officer will confirm that
  - ✓ amended version of the protocol and
  - ✓ Changes or modifications in the amended documents is present
- The Secretariat will check for completeness submission package and inform the Principal required documents at the earliest, if any

5.2 Notify the Chairperson of the IEC

- After receipt of the amendment package, the Secretary/ Chairperson of the IEC verbally
- The Secretariat will send the request for and related documents to the Member Secretary receipt of the package with the Protocol

5.3 Determine whether full review or review by

- After review of the materials, the Chairperson whether the protocol requires a full board
- The amended protocol / protocol related documents of the following criteria are met:
- The Protocol amendment which increases risk Chairperson and/ or the Member Secretary include but is not limited to:
  a. additional treatments or the deletion of
  b. Changes in inclusion/exclusion criteria
  c. change in method of dosage formulation
  d. a significant change in the number of research participants (if the decrease/increase in the number of participants alters the fundamental characteristics of the study, it is significant)
  e. a significant decrease or increase in dosage amount

The Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form *AX 01/SOP 09/V1*.

- The request form should:
  - ✓ state/describe the amendment
  - ✓ provide the reason for the amendment
  - ✓ state any untoward effects with original protocol
  - ✓ state expected untoward effects, if any because of the amendment
- The Administrative Officer will confirm that the:
  - ✓ amended version of the protocol and related documents is present
  - ✓ Changes or modifications in the amended version are underlined or highlighted.
- The Secretariat will check for completeness of the contents of protocol amendment submission package and inform the Principal Investigator telephonically to submit the required documents at the earliest, if any of the documents are missing / incomplete.

5.2 Notify the Chairperson of the IEC

- After receipt of the amendment package, the Secretariat will inform the Member Secretary/ Chairperson of the IEC verbally.
- The Secretariat will send the request for amendment memorandum and the protocol and related documents to the Member Secretary / Chairperson within 7 working days of receipt of the package with the Protocol Amendment Assessment Form *AX 01/SOP 09/V1*.

5.3 Determine whether full review or review by designated members.

- After review of the materials, the Chairperson / Member Secretary will determine whether the protocol requires a full board review.
- The amended protocol / protocol related document will require Full Board review if any of the following criteria are met:
- The Protocol amendment which increases risk to study participants, as judged by the Chairperson and/ or the Member Secretary, such as a change in study design, which may include but is not limited to:
  a. additional treatments or the deletion of treatments
  b. Changes in inclusion/exclusion criteria.
  c. change in method of dosage formulation, such as, oral changed to intravenous
  d. a significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
  e. a significant decrease or increase in dosage amount

- If the Chairperson and / or the Member Secretary decides the protocol requires full board IEC review or review by two/more IEC members or review by Member Secretary/ Chairperson,
- The Chairperson/Member Secretary will indicate this decision on the Protocol Amendment Assessment Form *AX 01/SOP 09/V1*. The Form *AX 01/SOP 07/V1* will be used to nominate members by the Chairperson.

5.4 Distribution to IEC members

- The following documents will be distributed to the designated IEC members as per the decision regarding review
  - The amendment's revision documents to clearly identify each change.
  - Protocol Amendment Assessment Form *AX 01/SOP 09/V1*.
- Whenever the decision is Full Board review, the Secretariat shall summarise the points for discussion regarding the amended protocol/protocol related documents and shall place the protocol amendment request on the agenda for discussion at the next convened meeting.

5.5 Protocol Amendment Review Process

- The IEC member will review the amended documents and write his/her comments in the form- *AX 01/SOP 09/V1*.
- The reviewer may request the secretariat to keep the documents for full board discussion after review.
- The IEC members performing the review must sign and date the form i.e. *AX 01/SOP 09/V1* and return this to the Secretariat after the review.

5.6 IEC Decision

- In case the project is kept for full board review, the Member Secretary / designated member will read the comments on the amended protocol/ protocol related documents in the meeting. The Chairperson shall call for voting on the proposed amendment to:
  - Approve the protocol amendment
  - Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full IEC review/ IEC review.
  - Suspend the entire study, until further information is obtained
  - Not approve the amendment request, stating the reason – but allow the study to continue as previously approved.
- The Secretariat will record the decision reached on the proposed amendment in the minutes of the meeting.
- The decision by the designated reviewers may be
  - Approved
  - Disapproved

- Suggested Recommendation
- Next full board discussion

5.7 Communication of the Decision to the Principal Investigator

- If the IEC approves the protocol/ informed consent documents (ICDs) amendment, the Secretariat staff will send a signed and dated Amendment Approval Letter i.e. AX 02/SOP 09/V1 to the Principal Investigator (PI) within 14 days of the meeting. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 days of the meeting.
- The Member Secretary shall inform other members about the decision taken on the amended document/s at the next full board meeting.

5.8 Store documents

- The Administrative Officer will place the original completed documents, the amended version of the protocol and related documents, the amendment assessment form in the same project file sequentially

6. Glossary

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the IEC. In the course of the study, the PI may decide to make changes in the protocol.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2013)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2013)

[3] Code of Federal Regulation (CFR), 21 §56.110, the United States of America, 1998.

8. Annexure

ANNEXURE 1	*AX 01/SOP 09/V1*	Protocol Amendment Request and Assessment Form
ANNEXURE 2	*AX 02/SOP 09/V1*	Project Amendment/Document Amendment Approval letter

Type of review :- (Decision by the Chairperson/ Member Secretary) Review by Member Secretary/ Chairperson ☐ Review by designated IEC members ☐ Full Board discussion and review ☐
Comments of the reviewer :- _____ _____
Decision: ☐ Approved ☐ Suggested Recommendation(s) ☐ Disapproved ☐ Next full board discussion
Name of IEC Member / Member Secretary / Chairperson reviewing the project: _____ Signature with Date:_____
Final Decision: Approved YES ☐ No ☐ If disapproved, reasons for disapproval_____ _____ Further revision or modification required
Any Other ☐
Signature of the Chairperson/Member Secretary:_____ Date:_____

Annexure 2

AX 02/SOP 09/V1

Protocol Amendment/Document Amendment Approval letter

To

XXXXX (PI)

Department

Ref: - IEC No. Project title

Dear Dr._____

We have received from you the following document (s).

1.

Annexure 1

AX 01/SOP 09/V1

Protocol / Protocol related documents Amendment Request and Assessment Form

IEC Protocol Number:	
Protocol Title:	
Principal Investigator and Department:	
Approved date:	No. of amendment:

- State/describe the amendment :type of document/ part of document amended
- Reasons for the amendment
- Impact of your amendment on your present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)

Have the changes modifications in the amended versions been highlighted/ underlined?
Yes ☐ No ☐

Name of Principal Investigator: _____
Signature with Date: _____

2.

At the Institutional Review Board meeting held on _____ the above mentioned documents were reviewed.

After consideration, the IEC has decided to approve:

(a) The aforementioned study-related documents OR

(b) The following documents:

1.
2.

The members who attended this meeting held on _____ at which the above mentioned document was discussed are listed below.

1.
2.
3.

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Review Board.

OR

After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

Yours truly,

Signature of Chairperson/ Member Secretary
with Date
IEC

Title: Continuing Review of Study Protocols

SOP Code: SOP 10/V1 dated 22nd August 2016

Authors:

Dr. Milind Joshi, (Member , IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

1/9/2016

Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	3
6	References	5
7	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Institutional Ethics Committee (IEC). The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving research participants at intervals appropriate to the degree of risk. All the projects approved by the Institutional Ethics Committee will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

3. Responsibility

It is the responsibility of the IEC Secretariat to remind the IEC and the principal investigators regarding study protocols that should be continuously reviewed. All the approved protocols will be reviewed annually (at least once a year). The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC meeting wherein the project is finally approved or can be taken subsequently based on the SAE reports, monitoring reports, adequacy documentation procedures followed by the investigators or new safety data received.

The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

The IEC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as approval to continue the study; approval with recommendations; or disapproval.

4. Flow chart

No.	Activity	Responsibility
1	Determine the date of continuing review	IEC Secretariat and Chairperson
2	Notify the Principal Investigator or study team	IEC Secretariat
3	Manage continuing review package upon receipt	IEC Secretariat
4	Notify the members of the IEC	IEC Secretariat
5	Prepare meeting agenda	IEC Secretariat

6	Review of Continuing review report	IEC Secretariat, Members, and Chairperson
7	Store original documents	IEC Secretariat
8	Communicate the IEC decision to the Principal Investigator	IEC Secretariat

5. Detailed instructions

5.1 Determining the date of continuing review

- The Administrative Officer will look through the document archives/master chart of projects approved by the IEC for the due date of continuing reviews.
- The Secretariat will plan for continuing review of annual progress reports to be reviewed as close as possible to the due date or the anniversary of the effective date (date of original approval) of the protocol.

5.2 Notifying the Principal Investigator or the study team

- If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format mentioned in *AX 01/SOP 10/V1* within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to
  a) A letter of reprimanding the Investigator.
  b) Not reviewing future projects from the PI for a specified period of time.
  c) A letter asking the Investigator to put recruitment of new participants on hold.

5.3 Managing the continuing review package upon receipt.

- The Secretariat will receive a package (soft and hard copy) submitted by the Study Team of continuing review for each approved protocol. Only one set (soft and hard copy) of continuing review report shall be submitted by the Principal Investigator to the IEC as per the format Continuing Review Application Form (*AX 02/SOP 10/V1).*

5.3.1 Verifying the contents of the package

- The Secretariat will make sure that the contents of the package include the following documents:
  - Continuing Review Application Form (*AX 02/SOP 10/V1)*
  - The Continuing Review Application Form duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 10/V1)* answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team,

any unexpected complications etc. have to be discussed in the attached narrative.

- The Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form (*AX 02/SOP 10/V1*).

5.3.2 Storing the continuing review package.

The Administrative Officer shall store the original package in the protocol specific file.

5.4 Notifying the Members of the IEC

- The Chairperson /Member Secretary will review the Continuing Review Application Form (*AX 02/SOP 10/V1)* and inform about the decision to the IEC members at a forthcoming full board meeting or place it before the IEC members at the Full Board meeting. The Chairperson can designate two IEC members (letter of nomination – *AX 01/SOP 07/V1*) to review the Study report and related documents and inform the decision to the other IEC members at the next full board meeting.
- The Secretariat will send the Continuing Review Application Form (*AX 02/SOP 10/V1)* to the designated IEC members (letter of nomination – *AX 01/SOP 07/V1*)

5.5 *Protocol Review Process*

The IEC Chairperson/ Member Secretary / Members will use the Continuing Review Application Form (*AX 02/SOP 10/V1)* to guide the review and deliberation process. The IEC members could arrive at any one of the following decisions at the IEC meeting:

1. Noted : The IEC approves the continuation of the above mentioned project without any modifications (as per the format *AX 03/SOP 10/V1*)
2. Modifications recommended: Protocols that have been suggested modifications by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC within one month for re-review.
3. The project cannot be continued: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator. This decision shall be recorded by the Member Secretary on *AX 02/SOP 10/V1*.

   - The IEC Chairperson will sign and date the IEC decision on Continuing Review Report after a decision has been reached.
   - The IEC Secretariat will maintain and keep the IEC Decision forms and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.6 *Storing the original documents.*

Place the original completed documents *AX 01/SOP 10/V1* with the other documents in the Continuing Review Package in the protocol file.

5.7 Communicating the IEC Decision to the Principal Investigator

The Secretariat will notify the Principal Investigator of the decision. The letter must be sent to the Principal Investigator within 14 days of the Meeting at which the report was discussed or the decision taken earlier by the Chairperson regarding the Continuing review was informed to the IEC members.

6. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016)

7. Annexure

Annexure 1	*AX 01/SOP 10/V1*	Reminder letter by the IEC to investigator
Annexure 2	*AX 02/SOP 10/V1*	Continuing Review Application Form
Annexure 3	*AX 03/SOP 10/V1*	Project Report Approval letter

Annexure 1

AX 01/SOP 10/V1

Reminder letter by the IEC to Investigator

Date:-

Name of Principal Investigator:-

Department:-

Ref: - Project Title: XXXXXX

The above referenced project was approved by the IEC on XXXXXXX and was due for Continuing Annual/ Periodic Review by the IEC. You are requested to submit an Annual/ Periodic status report in the prescribed format (Continuing Review Application Form *AX 02/SOP 10/V1*) at the earliest, on or before XXXXX.

Signature with date _____

Member Secretary/ Chairperson _____

Annexure 2

AX 02/SOP 10/V1

Continuing Review Application Form

Date: _____

Protocol No.:	**Date of IEC approval:**
Protocol Title:	
Principal Investigator : **Department :**	

Summary of protocol participants:

____ No. of participants approved by IEC

____ No. of recruited participants

____ No. of ongoing participants

____ No. of Completed participants

____ No. of participants who refused to consent

Have any participants been withdrawn from this study?

- ☐ No
- ☐ Yes (state the number and reasons for drop-outs of each participant, attach separate sheet if needed)

_____

_____

Impaired participants

- ☐ None
- ☐ Physically
- ☐ Cognitively
- ☐ Both

Have there been any amendments in protocol/ Informed Consent Document since the last review?

- ☐ NO
- ☐ YES

Were these protocol/ Informed Consent Document (ICD) amendments approved by IEC?

- ☐ No

Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC/IEC's evaluation of the risk/benefit analysis of participants involved in this protocol?

- ☐ No
- ☐ Yes (attach separate sheet if needed)

_____

Have any unexpected complications or SAEs been noted since last review at our site?

- ☐ No
- ☐ Yes (attach separate sheet if needed)
- ☐ No. of patients who had SAEs- _____
- ☐ Whether reports of SAEs at have been submitted to the IEC- _____
- ☐ Whether reports of SAEs at other sites have been submitted to the IEC-_____
- ☐ Types of adverse events with nos. of participants- _____

_____

- ☐ Number of unexpected AE

Have any participating investigators been added or withdrawn since last review?

- ☐ No
- ☐ Yes (Identify all changes in the attached narrative)

❑ Yes If no, mention the amendments not approved _____ _____ Which protocol amendment is the site following at this date _____ Which ICF amendment is the site following at this date _____	**Is report of interim data analysis available?** ❑ No ❑ Yes (submit as an attachment) **Is report of the data safety and monitoring board available?** ❑ No ❑ Yes (submit as an attachment) **Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?** ❑ No ❑ Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date: _____

Assessment of Continuing Review Report by the IEC

To be reviewed by

- Chairperson / Member Secretary only and informed to the IEC members at Full Board ☐
- Full Board ☐
- Any 2 IEC members and informed to the IEC members at Full Board ☐

1. Names of IEC members: _____

_____

_____

_____

Signature with date
Chairperson/ Member Secretary

IEC Decision on the Continue Review Report

Decision

Approved and the project can be continued without any modifications ☐

Modifications recommended - requiring protocol resubmission ☐

State the recommendations:

Protocol should be discontinued __

State the reasons for discontinuation

Full Board discussion ☐

Any Other ☐

Signature of reviewer/s with date: _____

Final Decision on the Continue Review Report: _____

_____

Signature with date
Chairperson / Member Secretary

Annexure 3

AX 03/SOP 10/V1

Project Report Approval Letter

Name of the Principal Investigator:-
Department :-
Ref: - Project Title: _____
Sub: - Letter dated: _____

This is with reference to the above stated letter regarding the continuing review report of the above mentioned project. The Continuing Review Report was reviewed in the IEC meeting held on XXXXXXXX and was noted.

The IEC allows continuation of the above mentioned project without any modifications.

You are requested to submit the next continuing review report within 1 month of the due date i.e. on or before XXXXX.

_____

Signature with date
Member Secretary / Chairperson

Date of approval:

Institutional Ethics Committee (IEC)
DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Title: Protocol Deviation/Non-Compliance/Violation

SOP Code: SOP 12/V1 dated 22nd August 2016

Authors:

Dr. Milind Joshi, (Member, IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016

Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	3
6	Glossary	5
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for taking action(s) when investigator(s)/trial site(s) fail(s) to:

- follow the procedures written in the approved protocol
- comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the Institutional Ethics Committee (IEC) for the conduct of human research
- respond to the IEC requests regarding statutory, ethical, scientific or administrative matters

2. Scope

This SOP applies to all IEC approved research protocols involving human research participants.

3. Responsibility

It is the responsibility of the IEC Secretary /Chairperson to bring to the notice of the Full Board if it is brought to their notice that investigators have failed to

- follow the procedures written in the approved protocol
- comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the IEC for the conduct of human research
- respond to the IEC requests regarding statutory, ethical, scientific or administrative matters

The Secretariat is responsible for collecting the Deviation/Non-compliance/Violation Form *AX 01/SOP 12/V1* and recording the decision of the IEC in the form.

4. Flow chart

No.	Activity	Responsibility
1	Detection of Protocol deviation/ non-compliance/ violation	IEC members / Secretariat
2	Noting protocol deviation/ non-compliance/ violation	IEC members / Secretariat
3	Board discussion, decision and action	IEC members, Member Secretary and Chairperson
4	Notify the Principal Investigator	IEC Secretariat,
5	Keep records and follow up	IEC Secretariat

5. Detailed instructions

5.1 Detection of Protocol deviation/ non-compliance/ violation

Protocol deviation/non-compliance/violation may be detected in one the following ways (but not limited to those listed below):

1. Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC
2. The IEC members performing monitoring of the project at trial site may detect protocol deviation/non-compliance/violation if the project is not been conducted as per protocol/ national/international regulations.
3. The Secretariat may detect protocol deviation/non-compliance/violation from failure to comply with statutory requirements/failure to respond to requests from IEC within reasonable time limit/failure to respond to communication made by IEC.
4. The IEC members may detect protocol deviation/non-compliance/violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization.
5. The IEC secretariat and/ or IEC members may become aware of a protocol deviation/ non-compliance/ violation while reviewing study-related documents including reports filed in by the Principal Investigator.
6. Communication/ complaint/ information received from research participant who has been enrolled or any individual who has been approached for enrollment
7. Any report/ communication brought to the notice of Member, Secretary/ Jt. Secretary/ Chairperson of IEC by an independent person
8. Communication received from the Head of the Institution informing IEC about an alleged protocol violation/ non-compliance/ protocol deviation

5.2 Noting protocol deviation / non-compliance / violation by the Secretariat

1. The IEC members who have performed monitoring of a particular trial site and detect protocol violation will inform the Secretariat in writing within 2 working days.
2. The Secretariat will notify the Chairperson of any protocol deviation/non-compliance/violation from the project files/protocol deviation/non-compliance/violation letters (soft copy and hard copy) forwarded by the Principal Investigator/ from any source within 7 working days of receipt of the notification from principal investigator (PI) depending upon the seriousness of non-compliance. Whenever protocol violation has been observed, the Chairperson and/ or Member Secretary and /or two or more IEC members designated by the Chairperson of IEC will scrutinize (initial scrutiny) the violation/ non-compliance/ deviation for gravity and implications. This scrutiny could be conducted jointly/ individually at a meeting/ through telephone/ email/ any other mode of communication. The findings shall be documented individually or in the form of report by the IEC Secretary. Depending upon their judgment the IEC shall:

a. Ask PI for written clarification as soon as the deviation is received OR

b. The Secretariat will call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny OR

c. The Secretariat will put up the information and communication at the next full board meeting

5.3 Board discussion, Decision and Action

- If the protocol deviation / non-compliance / violation is detected by IEC member during monitoring visit he/she will present the protocol deviation / non-compliance / violation information.
- If detected by Secretariat/forwarded by Principal Investigator, the Member Secretary will present the protocol deviation / non-compliance / violation information.
- The Chairperson/IEC members will review the information available and take a decision depending on the seriousness of the violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by voting. The actions taken by IEC could include one or more of the following:
  - ✓ Inform the Principal Investigator that IEC has noted the violation/ non-compliance/ deviation and;
  - ✓ Direct the PI to ensure that deviations/non-compliances/violations do not occur in future and follow IEC recommendations.
  - ✓ Enlist measures that the PI would undertake to ensure that deviations/non-compliances/violations do not occur in future
  - ✓ Reprimand the PI.
  - ✓ Call for additional information.
  - ✓ Suspend the study till additional information is made available and is scrutinized.
  - ✓ Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
  - ✓ Suspend the study for a fixed duration of time.
  - ✓ Inform the Institutional Head/ Director/Dean.
  - ✓ Revoke approval of the current study.
  - ✓ Inform DCGI/ Other relevant regulatory authorities.
  - ✓ Keep other research proposals from the PI/ Co-PI under abeyance.
  - ✓ Review and/ or inspect other studies undertaken by PI/Co-PI.
  - ✓ Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
  - ✓ Any other action considered appropriate by the IEC for safeguarding the interests of the research participants participating in the current trial or in future trials.

- The action that the IEC will be based on:
  - [1] The nature and seriousness of the deviation / non-compliance/violation
  - [2] Frequency of deviation / non-compliance/violation in the study in the past
  - [3] Frequency of deviation / non-compliance/violation in previous studies conducted by the same PI/ Co-PI or in the same department
- This action will be recorded on *AX 01/SOP 12/V1* by the Member Secretary.

5.4 Notifying the Principal Investigator

- The Secretariat will send a notification signed by the IEC Chairperson to the Principal Investigator **within 14 days of the meeting,** if the decision was 'request the Principal Investigator not to perform such deviations/non-compliances/violations in future'.
- The Secretariat will send a project suspension/termination letter signed by the IEC Chairperson to the Principal Investigator **within 1 working day of the meeting,** if the decision was 'suspend the study till further information available/terminate approval of the current study'
- If the decision was 'refusal of subsequent project applications from the Principal Investigator, this notification letter signed by IEC Chairperson will be sent to the Principal Investigator **within 14 days of the meeting**.
- One copy of all letters shall be kept in the project file by the Secretariat.

6. Glossary

Non-compliance / Violation	The IEC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FDA regulations and/or fail to respond to the IEC request for information/action.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - *www.who.int/tdr/publications/publications/* (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016)

8. Annexure

Annexure 1 *AX 01/SOP 12/V1* Deviation/Non-Compliance/Violation Record

Institutional Ethics Committee (IEC)
DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Annexure1

AX 01/SOP 12/V1

Deviation / Non-Compliance / Violation Record

IEC Protocol no.:	
Study Title:	
Principal Investigator:	
Department:	
☐ Deviation from protocol ☐ Violation	☐ Non-Compliance
Description of deviation (s)/violation(s)	
Corrective Actions Taken by the Principal Investigator:	
Reported by (Name of Principal Investigator/ Study Team Member):	
Signature with date:	

Institutional Ethics Committee (IEC)
DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Provisional Decision by the Reviewer (Member Secretary and/or Chairperson and/or IEC Member)

- ☐ Noted
- ☐ Request the Principal Investigator not to perform such deviations/non compliances/violations in future
- ☐ Specific recommendations stated below to be followed

- ☐ Suspend the study till the IEC recommendations are implemented
- ☐ Suspend the study till information available
- ☐ Terminate approval of the current study

Reasons for termination

- ☐ Refuse subsequent applications from an investigator cited for non-compliance.
- ☐ To discuss at the full Board meeting
- ☐ Any other _____

Reviewed by
Name:
Signature with date:

Discussion of the protocol deviation/violation at the

- ☐ Emergency meeting on _____
- ☐ Next Scheduled full board meeting on _____

Final decision at the full board meeting held on _____

_____

Signature with date
Chairperson / Member Secretary

Title: Management of Premature Termination of the study

SOP Code: SOP 13/V1 dated 22nd August 2016

Authors:

Dr. Milind Joshi, (Member, IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

2016/01/09

Dr. Ravindrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	References	4
7	Annexure	4

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) proceeds and manages the premature termination of a research study. Protocols are usually terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by IEC that is being recommended for termination before its scheduled completion.

3. Responsibility

It is the responsibility of the IEC Chairperson to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the premature termination process.

4. Flow chart

No.	Activity	Responsibility
1	Receive recommendation for study termination	IEC Secretariat
2	Review and Discuss the Termination Package	IEC members / Chairperson
3	Notify the Principal Investigator	IEC Secretariat
4	Store the Protocol Documents	IEC Secretariat

5. Detailed instructions

5.1 Receipt of recommendation for study termination.

- The Secretariat will receive recommendation and comments from DSMB, Principal Investigator (PI), Sponsor, Regulator or other authorized bodies for premature termination of study protocol.
- The Secretariat will sign and date the package upon receipt.
- The IEC members/Chairperson can prematurely terminate the study if:
  1. Protocol non-compliance/violation is detected and IEC decision is to terminate the study (SOP 12/V1)
  2. SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
- The Secretariat will inform the Principal Investigator to prepare and submit a Premature Termination Report as per the format *AX 01/SOP 13/V1* (available in the IEC office).

- The Secretariat will receive the study protocol termination report (soft and hard copy) and submitted by the Principal Investigator and will check the completeness of the information, including accrual data since the time of the last continuing review.
- The Premature Termination Report *AX 01/SOP 13/V1* signed and dated by the Principal Investigator shall contain a brief written summary of the protocol, its results, and accrual data.

5.2 Reviewing and discussing the Termination Package.

- The Secretariat will inform the Chairperson regarding the recommendation for premature termination of study protocol and the termination report to the Chairperson within 14 days. The Chairperson shall review the results, reasons and accrual data and either call for an emergency meeting or discuss the report at the regular Full Board meeting.
- The Secretariat will arrange for an Emergency meeting and follow instructions as per SOP 17/V1 or put this in the agenda for the Full Board meeting as per SOP 16/V1
- The Member Secretary in the meeting will inform members of the premature termination of the project and the IEC members will review the Premature Termination Report *AX 01/SOP 13/V1*
- The Chairperson shall sign and date the study termination report in acknowledgment and approval of the termination.
- If the Premature Termination Report is unclear or more information is required from the Principal Investigator, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- If a letter containing comments by the IEC is sent to Principal Investigator, on receipt of the reply letter, it is reviewed as per the steps in 5.2 will be performed by the Secretariat.

5.3 Notifying the Principal Investigator.

- The Secretariat will make notification letter acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination. In case a letter is sent seeking clarifications/information regarding the premature termination, the principal investigator shall send a written response within 60 days of receiving the letter. If the PI does not comply, the matter will be put to the full board meeting for discussion.
- The Secretariat will send the notification letter to the principal investigator within 14 days after the meeting.

5.4 Store the protocol documents.

- The Secretariat will keep the original version of the Premature Termination Report *AX 01/SOP 13/V1* in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 5 years from the date of project Termination.

6. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 31st August 2016).

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

7. Annexure

ANNEXURE 1 *AX 01/SOP 13/V1* Premature Termination Report

Annexure 1

AX 01/SOP 13/V1

Premature Termination Report

IEC Protocol no.:			
Protocol title:			
Principal Investigator:			
Department:			
IEC approval date:		Date of last Annual/ Periodic status report submitted to IEC:	
Starting date:		Termination date:	
No. of participants enrolled:		No. of participants completed:	
No. of ongoing participants:		No. of drop outs: Reason for each drop-out	
SAEs (total no.): _____	Whether SAEs were reported to the IEC? Yes ☐ No ☐		
Brief summary of results: (use extra blank paper, if more space is required). _____			
Reason/s for termination: _____			

Signature with date of Principal Investigator: _____

Discussed at the IEC meeting held on _____

Action taken:

☐ Approval of the Premature Termination of the project

☐ Requires more information/ action as follows: _____

_____

_____

_____

Signature with date
Chairperson, IEC

Title: Constituting SAE Subcommittee

SOP Code: SOP 14(A)/V1 dated 22nd August 2016

Authors:

Dr. Amrut Mahajan, (Member , IEC) 01/9/2016

Reviewed by:

Dr. Devendra R. Chaudhari,(Member Secretary, IEC) 01/9/2016

Approved by:

Dr. Ravinadrakumar Bakal, (Chairperson, IEC)
(Signature with Date) 01/9/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	1
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	References	10

1. Purpose

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the SAE Subcommittee.

2. Scope

The SOP applies to all activities performed by the SAE Subcommittee.

3. Responsibility

It is the responsibility of the Institutional Ethics Committee members and the Secretariat to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

4. Flow Chart

No.	Activity	Responsibility
1	Composition of the SAE Subcommittee	Head of the Institute ,Chairperson, IEC Members and Secretariat
2	Membership requirements	Head of the Institute , Chairperson,
3	Tenure of Membership	Chairperson, IEC Members and Secretariat
4	Initiation of the process of appointment	Secretariat
5.	Appointment of new members	Head of the Institute
6.	Resignation and disqualification of members	IEC Members and Secretariat
7.	Conditions of appointment	IEC Members and Secretariat
8.	Selection and appointment of Head of the SAE subcommittee	Head of the Institute
9.	Quorum requirements	IEC Members and Secretariat

5. Detailed Instructions

5.1 Ethical basis

Serious Adverse Event (SAE) Subcommittee of the Institutional Ethics Committee' (IEC) first established in 21st April 2009. The SAE Subcommittee will review all serious adverse events (SAE) and unexpected adverse events (UAE) and adverse events (AEs)at this site / other sites in all types of research studies involving human participants approved by IEC.

The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

In evaluating all the adverse event reports, the SAE Subcommittee is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.

The SAE subcommittee attempts to keep itself informed of the requirements and conditions of the various localities where proposed research is being considered.

The SAE Subcommittee is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004), 59th WMA General Assembly, Seoul, October 2008.

It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human rights and Biomedicine (1997).

The SAE Subcommittee will work according to its established Standard Operating Procedures based on the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO, 2000), International Conference on Harmonization- Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2016 and 8th February 2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006). The mandate will be

a. To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
b. Provide public assurance of that protection
c. To ensure appropriate compensation as per Schedule Y, 30th January 2016 amendment is provided to the research participants.

The SAE Subcommittee is established and functions in accordance with the relevant national law and regulations in force from time to time.

5.2 Composition of the SAE Subcommittee

The SAE Subcommittee will be appointed by the **Head of the Institution (HOI)**.
The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
The SAE Subcommittee will be composed of at least 5 and a maximum of 10 members.

The members preferably should be from medical and scientific backgrounds.

The Composition shall be as follows:

- ✓ Head of the SAE Subcommittee (who is a member of the IEC)
- ✓ One Executive Secretary (who is a member of the IEC)
- ✓ Any IEC member with post graduate qualifications in the discipline of Medicine
- ✓ Atleast one member possessing post graduate degree in the subject of Pharmacology (who is the member of the IEC)

Resignation: An SAE Subcommittee member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

Disqualification for conduct unbecoming of an SAE Subcommittee member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an SAE Subcommittee member.

(i) The process will be initiated if IEC Chairperson or Head of SAE Subcommittee receives a communication in writing (provided by IEC member) alleging misconduct by a SAE Subcommittee member.

(ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned SAE Subcommittee member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of SAE Subcommittee member.

(iii) The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend him/ her.

(iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

Disqualification for not attending IEC meetings: A SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend more than 5 regular consecutive SAE Subcommittee meetings without prior intimation. The process conducted will be as follows:

(i) The Head of SAE Subcommittee will inform Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE Subcommittee.

(ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting

(iii) A written communication will be sent to the concerned SAE Subcommittee member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned SAE Subcommittee member will be allowed to state his/

- ✓ Atleast one member possessing post graduate degree in the subject of General Medicine (who is the member of the IEC)
- ✓ IEC Secretary will be Ex-Officio member of the SAE Subcommittee.
- ✓ The requirement, appointment and terms of membership will be the same as described below in sections 5.3 to 5.8.

The SAE Subcommittee may invite legal expert member of the IEC to provide opinion on the legal implication of adverse event.

5.3 Membership requirements

The Head of the Institute (HOI) is responsible for appointing the SAE Subcommittee members.

The Chairperson and IEC members can suggest names of potential IEC members but the final decision will remain with the HOI.

Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the SAE Subcommittee work.

5.4 Tenure of Membership.

The tenure of Institutional Ethics Committee members will be for a continuous period of two (2) years from the date of appointment.

The IEC secretariat will initiate the process of filling up the forthcoming vacancies two months prior to the end of tenure of a member of SAE Subcommittee. The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list provided by the IEC or otherwise. The retiring member will be eligible to be appointed for the new tenure consecutively three times.

5.5 Appointment of new members

a) The SAE Subcommittee members will be appointed by the HOI. New members will be appointed under the following circumstances:
   1. When a regular member completes his/ her tenure.
   2. If a regular member resigns before the tenure is completed.
   3. If a regular member ceases to be a member for any reason including death or disqualification.
   4. To fulfill the membership requirements as per 5.3 of this SOP

b) New members will be identified by the Chairperson according to the requirement (i.e. as per the composition specified in Section 5.2 of this SOP), membership requirement (Section 5.3 of this SOP) and provided the potential member fulfils the conditions of appointment as defined in 5.8 of this SOP after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

5.6 Resignation and Disqualification of Members.

her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson

(iv) The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.

The Chairperson or Head of SAE Subcommittee will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC

5.7 Conditions of appointment

Members will be appointed to the SAE Subcommittee if they accept the following conditions.

Willingness to publicize his/her full name, profession and affiliation.

Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

Willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member

5.8 Hierarchy

There will be one SAE Subcommittee-Head, one executive Secretary of SAE Subcommittee

The executive Secretary will be the guardian of all documents in the possession of the committee. In case of anticipated absence, the head of SAE subcommittee will nominate a SAE subcommittee member as Acting Executive Secretary. The Acting executive secretary will have all the powers of the executive secretary of the SAE subcommittee for that meeting.

Other SAE Subcommittee members will be regular committee members with equal ranking.

The Head of the SAE Subcommittee will be appointed by the Head of the Institute,

The executive secretary, will be elected by and from amongst the SAE Subcommittee members for 2 years term. The executive secretary may be re-elected any number of times. Should he/she resign or be disqualified, the SAE Subcommittee members will elect a replacement for another term.

5.9 Head of the SAE Subcommittee

The Head of the SAE Subcommittee will be appointed by the Head of the

Institute. The Head of the SAE Subcommittee will be affiliated to the institution.

The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports.

The Head of the SAE Subcommittee will sign minutes of the SAE Subcommittee meeting.

In case of anticipated absence, the head of SAE subcommittee will nominate a SAE subcommittee member as Acting Head. The Acting Head will have all the powers of the Head of SAE subcommittee for that meeting.

5.10 Functions of the Executive secretary of the SAE Subcommittee

1. To receive adverse event reports
2. To organize an effective and efficient tracking procedure for each onsite adverse event report received.
3. To inform the adverse events (serious and unexpected) reports to other members of the SAE Subcommittee.
4. To schedule and organize the SAE Subcommittee meetings
5. To prepare and maintain meeting agenda and minutes.
6. To prepare the communication letters related to the adverse event reports.
7. To communicate with the IEC members and applicants/ investigators.
8. To provide necessary administrative support for SAE Subcommittee related activities.
9. To ensure adherence of the SAE Subcommittee functioning as per SOPs

5.11 Functions of the IEC Secretariat

- The IEC Secretariat will perform the functions as mentioned in SOP 02/v3.3 for the SAE Subcommittee

✓ **Functions of the and Administrative Manager, Officer/s, Executive Assistant (*AX 01/SOP 02/V3.3*)**

1. To support the executive Secretary in executing functions of the SAE Subcommittee.
2. To prepare the agenda of the SAE subcommittee with help of Secretary of the SAE Subcommittee. The agenda of the SAE Subcommittee will include the information on SAE/ UAE at the site in the following format:

Participant ID	Letter no./ and date of reporting	Type of report	Type of SAE/ UAE	Date of onset	whether study drug withheld	Outcome	Causality in the opinion of PI

The agenda will also include information about onsite AE reports and SAE/UAE reports for the SAE /UAE occurring at other trial sites

3. To prepare the minutes (to be prepared within 5 working days of the meeting) with the help of the Secretary of the Subcommittee The minutes of the SAE Subcommittee will include the information on SAE /UAE at the site in the following format:

Participant ID	Letter no./ and date of reporting	Type of report	Type of AE/SAE/ UAE	Date of onset	whether study drug withheld	SAE Outcome	Causality in the opinion of PI	Recommendation (s) by the SAE Sub Committee

The minutes will also include the notification /recommendation on the onsite AE reports and other site SAE/UAE reports

4. To perform any other functions as instructed by executive Secretary/ Head of the SAE Subcommittee.

5.12 Roles and Responsibilities of the SAE Subcommittee members

To attend the SAE Subcommittee Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

To review, discuss and consider adverse event reports submitted for evaluation.

To review Serious Adverse Event and unexpected adverse reports and recommend appropriate action(s) as follows:

- The SAE /UAE reports will be reviewed completely in the SAE subcommittee meeting with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2016)
- The SAE subcommittee while reviewing may solicit opinion of one or more independent consultant (s) in writing, if the Sub-committee decides to consult experts. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality cause and abide by the rules and regulations of IEC or the necessary confidentiality documents are signed. The independent consultant would be requested to provide an opinion in writing within 3-5 working days, depending upon the gravity and seriousness.
- The following decisions/actions including the following but not limited to, are listed below:

1. Note the information about the SAE in records for future reference

2. To opine on compensation entitled to research participants (as per Drugs and Cosmetic Act 1940, Schedule Y - amendment 20th January 2005, 30th January 2016) experiencing Serious Adverse Event and unexpected adverse events and adverse events and recommend appropriate action(s)
3. Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation
4. Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier).In case of pregnancy as SAE to send follow up reports of the child in utero and post delivery of the baby till 1 year

If appropriate to the discussions, the recommendation regarding a specific action or combination of actions to be taken is arrived at by the SAE subcommittee meeting. The recommendations will be communicated to the IEC within 5 working days.

To maintain confidentiality of the documents and deliberations of the SAE Subcommittee meetings.

To declare any conflict of interest.

To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat

To carry out the work delegated by Head of the SAE Subcommittee

To assist Head of the SAE Subcommittee in carrying out IEC work as per SOPs

5.13 Quorum Requirements

The SAE Subcommittee meeting will be held as scheduled provided there is quorum. For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), executive secretary and Head / Acting head of the SAE subcommittee.

5.14 Responsibilities of the SAE Subcommittee

The SAE Subcommittee primary responsibilities will be protection of safety, rights and confidentiality of the research participants.

The SAE Subcommittee will keep all information submitted to them confidential specially the proprietary information.

The SAE Subcommittee will maintain concise but clear documentations of its views on the each adverse event report.

The SAE Subcommittee will review the serious adverse event, unexpected adverse event and non serious adverse event of each research project at appropriate and specified intervals

The SAE Subcommittee will ensure that appropriate compensation is paid to the research participant as per Schedule Y, 30th January 2016.

6. References

[1] World Health Organization, Operational Guidelines for IEC Research, that Review Biomedical 2000. (Geneva 2000 www.who.int/tdr/publications/publications/- last accessed 31st August 2016) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016)

[2] CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects *http://www.cioms.ch/frame_guidelines_nov_2002.htm* (last accessed 31st August 2016)

[3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethical_guidelines.pdf* (last accessed 31st August 2016)

[4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) *http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm* (last accessed 31st August 2016)

[5] European Convention on Human rights and Biomedicine (1997).*http://conventions.coe.int/treaty/en/treaties/html/164.htm* (last accessed 31st August 2016)

Institutional Ethics Committee (IEC)
DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Title: **Review of Serious Adverse Events (SAE) Reports and Unexpected Adverse Events (UAE)**

SOP Code: **SOP 14/V1 dated 19th June 2016**

Authors:

Dr. Amrut Mahajan, (Member, IEC) 01/09/2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/9/2016

Approved by:

Dr. Ravinadrakumar Bakal, Chairperson, IEC
(Signature with Date) 01/9/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2

5	Detailed Instructions	3
6	Glossary	8
7	References	9
8	Annexures	9

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of adverse events (AE), serious adverse events (SAE) and unexpected adverse events (UAE) reported to the IEC by sites at DR. Ulhas Patil Medical College and Hospital for any study under the oversight of the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of AE, SAE and UAE reports submitted to the IEC.

3. Responsibility

It is the responsibility of the IEC to review AEs, SAEs and UAEs reported to the IEC. These could be AEs, SAEs, and UAE occurring at DR. Ulhas Patil Medical College and Hospital or other sites for the given project/related project.

4. Flow Chart

No.	Activity	Responsibility
1	Receipt of AE, SAE and UAE report	Secretariat
2.	Submission of AE, SAE and UAE report to the Subcommittee	Secretariat
3	Agenda and Minutes of the Subcommittee	Secretary of the SAE Sub-committee
4.	Review and discussion of SAE report at the Subcommittee meeting	SAE Subcommittee members
5.	Discussion/ Decision at the emergency IEC meeting	Members of the IEC
6.	Communication of the IEC decision about SAE review to the principal investigator	Secretariat
7.	Communication of the IEC decision about SAE review to the Chairperson of the Expert Committee constituted by the Licensing authority /DCGI	IEC chairperson

8	Discussion/ Information at the full IEC meeting	Member Secretary of the IEC board

5. Detailed Instructions

5.1 Onsite SAE and UAE

5.1.1 Receipt of SAE/UAE report

- The IEC Secretariat will receive the following documents within the specified time frame pertaining to SAE /UAE experienced by the research participants ON SITE for research proposals approved by the IEC:
  - i. On site SAE or UAE report to be submitted by the Principal Investigator within 24 hours of their occurrence as per the format specified in *AX 01/SOP 14/V1* (as per Appendix XI of Schedule Y)
  - ii. In the case of SAE, the report with due analysis will be submitted by the Principal investigator within 10 calendar days along with the format specified in *AX 02/SOP 14/V1*
  - iii. In the case of SAE, the report with due analysis will be submitted also by the sponsor within 10 calendar days along with the format specified in *AX 02/SOP 14/V1*
  - iv. The follow up reports of all on site SAE / unexpected AE reports till the event is resolved
- The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) or Sponsor as the case may be and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as a violation.
- The IEC Secretariat will sign and write the date on which the report is received.
- For all the onsite SAE/ UAE reports received at the IEC office, the Administrative Officer will forward these reports to the executive secretary of the SAE Subcommittee within two working days.

5.1.2 Review of SAE, UAE Reports

- Secretary of the SAE Subcommittee will review the SAE /UAE report and arrange a meeting depending on the timelines.
- SAE and UAE reports submitted to the IEC will be reviewed by the SAE subcommittee at least weekly or more often (as needed).
- The constitution and functioning of the SAE subcommittee is described in SOP 14A.
- At the meeting, the members of the SAE subcommittee will review all the SAE/UAE reports received in the earlier week and submit a report stating the recommendations on the SAE/UAE report discussed in the meeting to IEC

5.1.3 Communication to the IEC

i. The IEC Secretariat will receive the minutes within 5 working days of the meeting of the SAE subcommittee and recommendation taken on the onsite SAE /UAE report.

ii. This report will be circulated to the IEC members *via* email and approval/ objection will be sought from the members in a period of 2 days.

iii. If approval is obtained from all the IEC members the decision will be communicated to the Licensing authority (DCGI) within 21 calendar days of the occurrence of the SAE.

iv. If the SAE is death then the decision in addition to DCGI will also be communicated to the Chairperson of the Expert Committee within 21 calendar days of the occurrence of the SAE.

v. If decision is that research participant is entitled for financial compensation an emergency IEC meeting will be scheduled within 7 days for the same (refer SOP 017/ V1)

vi. If objection is received from more than 2 IEC members an emergency IEC meeting will be scheduled within 7 days for the same.

- The decision taken at the emergency IEC meeting regarding the onsite SAE/UAE report will be communicated to the Licensing authority (DCGI) within 21 calendar days of the occurrence of the SAE. If the SAE is death then the decision in addition to DCGI will also be communicated to the Chairperson of the Expert Committee within 21 calendar days of the occurrence of the SAE

5.1. 4 Inform Investigator

- The IEC secretariat will draft a formal letter to the concerned Principal Investigator and inform him/ her about the IEC decision. This letter will be signed and dated by the Member-Secretary or Chairperson (IEC) and will be sent to the Principal Investigator within a period of 7 days from the date of the SAE subcommittee meeting.

- The Principal Investigator will be requested to reply to the query letter on the SAE report within 7 working days. If no response is received (within 7 days of dispatch of EC query letter) from the investigator regarding the query raised on the given SAE/UAE, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be informed by the member secretary of the IEC in the full board meeting and decision will be taken on case to case basis.

- The principal investigator will be requested to forward follow-up reports after due analysis of the SAE/unexpected AE report to the IEC within 10 calendar days of the occurrence of the SAE/unexpected AE report.

- The Administrative Officer will file a copy of the query letter in the study file.

5.1.5 Inform Licensing authority (DCGI)

- The Chairperson of the IEC will forward the letter describing the opinion on the SAE report death, along with the opinion on financial compensation, to the Chairperson of the Expert Committee constituted by the Licensing authority (DCGI) and also a copy to DCGI within 21 calendar days of the occurrence of the SAE-death.

- The Chairperson of the IEC will forward the letter the decision taken on the given SAE report (other than death)/unexpected adverse event report along with the opinion on financial compensation to the Licensing authority (DCGI) within 21 calendar days of the occurrence of the SAE/ unexpected adverse event.
- The Administrative Officer will file a copy of these letters in the study file.

5.2 Onsite AE

5.2.1 Receipt of AE report

- The IEC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the IEC:

  1. On site AE reports to be submitted by the Principal Investigator annually.
  2. In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.

- The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as violation.
- The IEC Secretariat will sign and write the date on which the report is received.
- For all the onsite AE reports received at the IEC office, the Administrative Officer will forward these reports to the executive secretary of the SAE Subcommittee within two working days.

5.2.2 Review of AE Reports

- AE reports submitted to the IEC will be reviewed by the SAE subcommittee at the scheduled meetings as per procedures described in SOP 14A and minutes communicated to IEC Secretariat

5.2.3 Inform Investigator

- The IEC secretariat will draft a formal letter to the concerned Principal Investigator and inform him/ her about the IEC decision on the concerned AE report. This letter will be signed and dated by the Member-Secretary or Chairperson (IEC) and will be sent to the Principal Investigator within a period of 7 days from the date of the SAE subcommittee meeting.

- The principal investigator will be requested to reply to the query letter on the AE report within 7 working days. If no response is received (within 7days of dispatch of EC query letter) from the investigator regarding the query raised on the given AE report, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be informed by the member secretary of the IEC in the full board meeting and decision will be taken on case to case basis.

5.2.4 Further action

- The Administrative Officer will file a copy of these letters in the study file.
- If deemed necessary Licensing Authority will be informed

5.3 SAEs occurring at other sites:

The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS and Appendix XI) in the form of soft copies only (CD) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:

Sr. No.	Country	MFR Control No.	Type of Report	SAE event	Date of onset of ADR	Date of ADR report	Outcome	Causality	
								Investigator	Sponsor

- For every SAE term use separate row. Do not club SAE terms.
- Please mentioned causality as related (R) or not related (NR)[do not use word possibly, unlikely, probable]
- The SAEs occurring at other sites will be reviewed by the Secretary of the SAE Subcommittee and informed to other members of the Subcommittee and discussed in the forthcoming scheduled Subcommittee meeting. The agenda and minutes of the SAE Subcommittee will include the information on SAEs at other sites.
- The discussion will be communicated by the SAE Subcommittee Executive Secretary to the Secretariat who will include it in the appropriate IEC agenda

5.4 During the Full board IEC meeting

- The IEC Member Secretary will read out the minutes of all the weekly SAE Sub-committee meetings including the recommendations/ decisions of the SAE sub-committee.
- In case of the AE/ SAE/UAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information

including updates on AE/ SAE/ UAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.

- If appropriate to the discussions and any issues put forth by SAE subcommittee, the issue can be re-discussed and decision can be arrived at by voting (a majority vote for a decision is 2/3rd majority of the members present and voting) or by consensus.

Actions are listed below:

- *Terminate the study*
- *Suspend the study till review is completed (safety monitoring of ongoing patients to be continued)*
- *Suspend the study till additional information is available*
- *Suspend the study for a specified duration of time*
- *Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents*
- *Suspend the study till amendments requested for by the IEC are carried out;*
- *Suspend enrollment of new participants;*
- *Suspend certain activities under the protocol*
- *Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial*
- *Direct the Investigator to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment*
- *Note the information about the SAE in records for future reference*
- *Request further follow up information and/ or additional details*
- *Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier)*
- *Any other appropriate action;*

The decision shall be recorded in the minutes of the full board IEC meeting

- If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, fax or email within 24 hours. Such a communication will be documented by the IEC Member-Secretary in the study file. A formal letter to the Principal Investigator informing

about the IEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

6. Glossary

Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Adverse Drug Reaction	In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.
IND	Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.
Unexpected adverse event	An adverse event, the nature or severity of which is not consistent with the applicable product information (eg: Investigator's brochure for an unapproved investigational product or package insert /summary of product characteristics for an approved product)
SAE (Serious Adverse Event)	The adverse event is SERIOUS and should be reported when the patient outcome is: **Death:** Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life-Threatening:** Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued

	use of the product would result in the patient's death. *Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.* **Hospitalization** (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.* **Disability** - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. *Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.* **Congenital Anomaly** - Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. *Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.* **Requires Intervention to Prevent Permanent Impairment or Damage** – Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient. Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2016).

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

[3] Nationwide Children's Hospital, Standard Operating Procedure: SAE Reporting and Review

http://etrac.ccri.net/CRI/Doc/0/2137HUSRMVKKFBHAT542EHDME8/011%20Adverse%20Event.p
df (last accessed31st August 2016)

8. Annexure

Annexure 1	*AX 01/SOP 14/V1*	Checklist for Serious Adverse Event & Unexpected Serious Adverse Event Submission
Annexure 2	*AX 02/SOP 14/V1*	Serious Adverse Event Analysis Report **(For SAE at the site)**

Annexure 1

AX 01/SOP 14/V1

Checklist for Serious Adverse Event & Unexpected Serious Adverse Event submission

Sr. No.	Details		
1.	Country (Name of the country should be specified)		
2.	SAE report of death or other than death, Please tick (✓)	Death ☐	Other than Death ☐
		Yes / No	Page No.
3.	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box		
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	Patient Details		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		

13.	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	**Details of the events**		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		

g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 2

AX 02/SOP 14/V1

Serious Adverse Event analysis Report

(For SAE at the site)

Sr. No.	Details		
14.	**Country (Name of the country should be specified)**		
15.	**SAE report of death or other than death, Please tick (✓)**	**Death** ☐	**Other than Death** ☐
		Yes / No	**Page No.**
16.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box**		
17.	Protocol Title		
18.	Protocol Study No./ ID /Code		
19.	Copy of Clinical Trial permission obtained from CDSCO		

20.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
21.	Sponsor(Address with contact no and Email)	What is the ... sponsor's ...	
22.	CRO (Address with contact no and Email)		
23.	Initial / Follow-up (FU)		
24.	In case of follow-up: Date & Diary no of initial or recently submitted report information	Has the par... ...ent ma...	
25.	**Patient Details**		
f)	Initials & other relevant identifier (hospital/OPD record number etc.)	If yes, for ho... such ...	
g)	Gender	If no, please ... ...ure it...	
h)	Age and/or date of birth	...ights regar... ...ons...	
i)	Weight		
j)	Height		
26.	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.	Signature ...	Pri...
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).	Name:	
15.	**Details of the events**		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.	Signature ... Note: Inform ... not ...	
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been		

	conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
17.	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)
What is the investigator's assessment for the amount of compensation to be paid?

Institutional Ethics Committee (IEC)
DR. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

What is the sponsor's assessment for the amount of compensation to be paid?

Has the participant made a claim? Yes No

If yes, for how much amount _____

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

_____

_____

_____

Signature of the Principal Investigator : Date:_____

For IEC office use only

Verified by:

Name: _____

(Signature with date of IEC administrative staff) _____

Note: Information not relevant to a particular SAE should be marked with NA

Title: Site Monitoring Visit

SOP Code: SOP 15/V1 dated 22nd August 2016

Authors:

Dr. Amrut Mahajan, (Member, IEC) 01/9/2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/9/2016

Approved by:

Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date) 01/9/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	5
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select a site for monitoring and how the site will be monitored.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the Institutional Ethics Committee (IEC) approved study protocols.

3. Responsibility

It is the responsibility of the designated IEC member(s) or designated qualified agent to perform on-site inspection of selected study site(s) of relevant projects it has approved.

The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	IEC members / Chairperson
2	Identification of monitors for site monitoring	Chairperson
2	Before the visit	IEC members / representative, Secretariat
3	During the visit	IEC members / representative
4	After the visit	IEC members /representative, Secretariat

5. Detailed instructions

5.1 Selection of study sites

- IEC will identify the site(s) for routine monitoring at the time of approval of the project depending upon the reason provided by any IEC member. This decision will be recorded in the IEC Decision Form - *AX 03/SOP 06/V1*.
- The Chairperson will identify and designate one or more IEC members or independent monitor to carry out routine monitoring of the study site.
- The reason for identifying a particular site for 'monitoring' will be provided to an IEC member. This cause could include any one or more of the following:
  - High number of protocol violations, or
  - Large number of studies carried out at the study site or by the investigator, or

- Remarkable number of SAE reports, or
- High recruitment rate, or
- Non-compliance, or
- Suspicious conduct, or
- Complaints received from participants, or
- Any other cause as decided by IEC.

- After discussion at an IEC meeting, decision regarding conducting 'monitoring' will be taken. The Chairperson will identify and select one or more IEC members or independent monitor to conduct monitoring of a site.

5.2 Before the visit

- The IEC Chairperson will designate an IEC member or appoint an Independent monitor to perform the task of monitoring. The selected member or independent monitor will be provided with an appointment letter in this regard. A copy of the appointment letter along with the agenda for monitoring (mentioned in SOP 15 Version 4 point no. 5.3) will be forwarded to the Principal Investigator of the site to be monitored. The independent monitor will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.

- The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator to be available for the monitoring visit.

- The IEC member(s)/ Independent monitor will:
  - Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.
  - The IEC member/Independent monitor will review the IEC project files for the study and site profile and make appropriate notes.
  - The IEC member/Independent monitor will be provided with relevant reference material/ documents related to the project that may have to be referred to during the study visits and collect the Site Monitoring Visit Report Form- AX 01/SOP 015/V1 from the Secretariat.

5.3 During the visit

- The IEC member/Independent monitor will
  - ✓ Check the log of delegation of responsibilities of study team
  - ✓ Check if the site is using latest IEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.

- ✓ Review the informed consent document to make sure that the site is using the most recent version,
- ✓ Observe the informed consent process, if possible,
- ✓ Review randomly selected participants files to ensure that participants are signing the correct informed consent,
- ✓ Observe laboratory and other facilities necessary for the study at the site, if possible.
- ✓ Review the project files of the study to ensure that documentation is filed appropriately.
- ✓ Review the source documents for their completeness.
- ✓ Collect views of the study participants, if possible.
- ✓ Fill the Site Monitoring Visit Report Form- *AX 01/SOP 015/V1*, sign and date it.

5.4 After the visit

- The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 015/V1 to* the IEC secretariat within *14 days* of conducting a site monitoring visit.
- The report should describe the findings of the monitoring visit. The member-secretary will present the monitoring report at the next full board IEC meeting and the concerned IEC member/ independent monitor will provide additional details/ clarifications to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - ➢ Continuation of the project with or without changes,
  - ➢ Restrictions on enrollment,
  - ➢ Recommendations for additional training,
  - ➢ Recruiting additional members in the study team,
  - ➢ Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
  - ➢ Suspension of the study, etc.
- The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 015/V1*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

6. Glossary

Independent Consultants/ Independent monitor	Many IEC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of IEC to perform the tasks on their behalf and later report their findings to IEC.
Monitoring visit	An action that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

8. Annexure

Annexure 1 *AX 01/SOP 15/V1* Site Monitoring Visit Report

Annexure 1

AX 01/SOP 15/V1

Site Monitoring Visit Report

IEC project no.	Date of the Visit:
Study Title:	
Principal Investigators:	
Department:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs including reasons:
Are the present study team members as per the list approved by the IEC ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is recent version of Informed Consent Document (ICD) used? ☐ Yes ☐ No	Comment:
Is it approved by the IEC? ☐ Yes ☐ No	Comment:
Whether consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been used? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs ☐ Yes ☐ No	Comment:
Is recent version of protocol used? ☐ Yes ☐ No	Comment:
Is it approved by the IEC? ☐ Yes ☐ No	Comment:

Any adverse events found? ☐ Yes ☐ No	Comment:
Any SAEs found? ☐ Yes ☐ No	Comment:
Were the SAEs informed to IEC within 7 working days? ☐ Yes ☐ No	Comment:
Any there any protocol non-compliance deviations/violations? ☐ Yes ☐ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit:_____hours	Starting from: Finish:
Name of IEC members and representatives who attended the monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on _____

_____

Signature with date
Chairperson, IEC

Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

SOP Code: SOP 16/ V1 dated 22nd August 2016

Authors:

Dr. Amrut Mahajan, (Member, IEC) 01/9/2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/9/2016

Approved by:

Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date) 01/9/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	7
7	References	8
8	Annexure	8

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of Institutional Ethics Committee (IEC) meetings.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular IEC meetings, divided into three stages: before, during and after the meeting.

3. Responsibility

It is the responsibility of the Secretariat to prepare the agenda for the IEC meeting and to ensure proper recording and dissemination of the minutes after the meeting is over. The Chairperson will review and approve the agenda and the minutes sent to him/her.

4. Flow chart

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a board meeting	IEC Secretariat
2	During the Meeting	IEC Secretariat, Members and Chairperson
3	After the Board Meeting and Preparing the minutes	IEC Secretariat/ Member Secretary
4	Approval of minutes	IEC members / Chairperson
5	Filing the minutes	IEC Secretariat

5. Detailed instructions

5.1 Before each Board meeting

5.1.1 Preparation of meeting agenda

- The Secretariat will prepare the agenda to include:
  1. All resubmitted protocols wherein decision was full board review.
  2. Review of Amended protocol or protocol-related documents, wherein decision was to put to Full Board review.
  3. Issues to be reported for consideration
     - Continuing review of study protocols
     - Review of Study Completion Reports
     - Review of premature study termination

- Review of Site Monitoring Visit Reports
- SAE reports/CIOMS forms/Safety letters (If forwarded by SAE Subcommittee)

4. Issues to be discussed including emergency concerns/ IEC policies/ training of Members/ revising SOPs/ any other issues raised by Member(s).
5. Any other matter referred for IEC opinion or issues to be informed to the members.
6. Reading and approving minutes of the previous meeting.
7. Minutes of the Meeting of SAE subcommittee.
8. Policy decisions of the meeting of IEC.
9. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

The Secretariat will collect and verify all forms/documents for completeness to keep all these papers in the meeting.

- The Secretariat will prepare the meeting agenda, according to the format in *AX 01/SOP 16/V1*.
- The Administrative Officer will schedule protocols in the agenda on a first-come first-serve basis.
- The Member Secretary will schedule the next meeting at the time of the previous scheduled meeting after consulting the Chairperson and the IEC members.
- Answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) from the investigators received 7 days before and other types of documents received 3 days prior to the date of full board IEC meeting will be included in the agenda.
- Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting, any study-related document received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next month's meeting for discussion EXCEPT where in the opinion of the IEC Secretary or Chairperson has direct bearing on the safety of the research participants (such as SAE report, major protocol violation). Such important matters will be taken up at the imminent meeting.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members telephonically and/ or via e-mail.
- The Secretariat will send via e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting.
- The Secretariat will make a room reservation for the scheduled meeting date and time.

- The Secretariat will make sure that the room, equipment and facilities are available in good running conditions and cleaned for the meeting day.

5.2 During the meeting

- The committee will endeavour to hold regular meetings at least once every month. The gap between any two meetings will not exceed 60 days. Even if there are no research proposals for review, the gap between two meetings will not exceed 12 (twelve) weeks. Regular meetings may not be held in the months of May and October/ November, when the college closes for vacation. Meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of:
  - ⇒ One basic medical scientist (preferably a pharmacologist),
  - ⇒ One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person),
  - ⇒ A clinician,
  - ⇒ A lay person from the community and
  - ⇒ A legal expert

  besides the Member Secretary and the Chairperson.
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc. and are required to sign a confidentiality agreement *AX 03/SOP03/V1* prior to attending the meeting.
- The Secretariat will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form *AX 02/SOP03/V1* from newly appointed members/ Guests/ observers/ Independent Consultants prior to the start of the meeting.
- The Secretariat will obtain the signatures of all the IEC members on the attendance register.
- The Secretariat will obtain from members the written conflict of interest *AX 02/SOP16/V1* prior to the start of meeting
- The Chairperson will initiate the meeting after ensuring that the quorum has been met. The Chairperson at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.
- The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.

- The Chairperson will decide if the Conflict of Interest is potentially significant enough to cloud the member's judgment. If yes, the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed.
- The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.
- The Member Secretary will present the agenda of the day's meeting for discussion.
- The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.
- In case of projects submitted for initial review; the detailed instructions given in SOP 06/V1 – section 5.10 are followed.
- Investigators who have been asked by the IEC secretariat to provide additional information or clarifications related to their project may do so by attending the IEC meeting. The discussion amongst IEC members will not be done while the investigator is in the meeting room.
- For other points on the agenda, the member secretary will present the gist of the matter/ read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.
- ***Decision making***

  The final decision on each proposal/ issue discussed in the meeting shall be by voting/consensus.

  - A majority vote for approval, disapproval, request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting.
  - Member(s) of the committee who is/are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
  - An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
  - An independent consultant invited for the meeting to provide opinion will not vote or participate in the decision making procedures of the committee.
  - Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.
- The schedule of the next meeting will be discussed and finalized by the members.

5.3 After the Board meeting and preparing the Minutes

- The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following:

⇒ Name of person preparing the minutes

⇒ Location where the meeting was held (city, state)

⇒ Meeting number, date/duration of the meeting (time of commencement and end)

⇒ Names of the IEC members and guests attending the meeting

⇒ Name of the individual serving as Chairperson of the meeting

⇒ Determination of a duly constituted quorum by the Chairperson to proceed with the meeting

- Requirements for each study or activity requesting Approval:

⇒ Sponsor's name, if applicable

⇒ Protocol number/date/version of protocol, when available;

⇒ Investigator's name;

⇒ Names of the Primary Reviewers who presented their findings

⇒ Discussion as deemed appropriate by the Chairperson

⇒ Follow-up action decided upon

⇒ Reference to the investigator approval letter that lists all changes requested by the board;

⇒ Determination of the next requested continuing review.

- Requirements for each study or activity requesting Expedited Review:
  - Sponsor's name; if applicable
  - Protocol number, if applicable
  - Investigator's name;
  - Lists of expedited approval requests and outcomes.
- Requirements for each Continuing Review Report:
  - Sponsor's name; if applicable
  - Protocol number, if applicable;
  - Investigator's name;
  - Indication of the Board's determination to continue, terminate, or amend the study;
  - Lists of recommendations or actions to be taken up with the investigator, if applicable.
- Requirements for each Adverse Event notification and Final Report:

- Sponsor's name; if applicable
- Protocol number, if applicable;
- Investigator's name;
- Report or summary of report provided by the SAE sub-committee;
- Actions deemed appropriate by the Board's review.

- Requirements for Termination of Approval:
  - Name of the Sponsor ; if applicable
  - Protocol number, if applicable;
  - Investigator's name; reason for termination.

5.4 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and presents the minutes to the Chairperson for review and approval within 7 working days of the meeting day.
- The Chairperson indicates approval by signing and dating the minutes.
- The Secretariat will email the minutes of the meeting to the IEC members after obtaining approval from the Chairperson.

5.5 Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Administrative Officer will file the IEC Decision Forms in the project files and place all correspondence in the appropriate files.
- The Secretariat will send a list of the studies approved and rejected by the IEC at the monthly meetings (title of the study with name of the Principal Investigator) to the Head of the Institute every month within 21 days of the IEC meeting.

6. Glossary

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number of IEC members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

8. Annexure

Annexure 1 *AX 01/SOP 16/V1* Agenda format

Annexure 1

AX 01/SOP 16/V1

Agenda Format

Agenda of the IEC Meeting

Meeting No IEC meeting mm/yyyy

Location of the meeting

Meeting Date

Meeting time

The Board meeting will proceed in the following sequences:

Period 1: Discussion of the points arising from the minutes of the previous meeting and presentation of agenda of the day's meeting and Declaration of Conflict.

Period 2: A] New Protocol Presentation, Review, Discussion and reaching a decision by voting to approve/raise queries,

B] Review the responses forwarded by the principal investigator to the query letter/ resubmitted protocols

C] Approve protocol amendment and related documents.

D] To review the continuing review report/ completion report/ final clinical trial report/ Annual report / Termination reports .

E] To review Protocol Deviations / Violations

F] To review other Letters related to projects

G] To review Monitoring reports

G] To inform about the IEC-II meeting and to review the policy decisions

H] To inform about the SAE Subcommittee meetings and to review

SAE/Safety reports.

I] Other points for discussion

Period 3: Issues reviewed and approved by the IEC member Secretary and Chairperson which are to be reported **for Consideration**

Period 4: **Issues to be informed to the members at Full Board** which are approved by the IEC member Secretary and Chairperson and letters already sent to the principal investigator

Period 5: Other issues of interest to the members

Annexure 2

AX 02/SOP 16/V1

Conflict of Interest form

Date:

To,

The Chairperson,

IEC

I hereby declare the conflict of interest for the project no. EC/ /

entitled,_____

as :

1. I am the investigator / co-investigator/Author/study team
2. I have Financial interest
3. _____
4. _____
5. _____
6. _____

in the project which will be discussed in today's meeting i.e. 27th May 2016.

Dr. _____

Member, IEC

_____

Chairperson,
IEC

Title: Conduct of Emergency Meeting

SOP Code: SOP 17/V1 dated 22nd August 2016

Authors:

Dr. DEVENDRA R. CHAUDHARI (Member Secretary, IEC) 01/09/16

Reviewed by:

Dr. RAHUL PRAKASH BHAVASAR (Member, IEC) 01/09/2016

Approved by:

Dr. Ravindrakumar Bakal, Chairperson, IEC (Signature with Date) 01/09/2016

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	3
7	References	3

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process for preparing for an emergency meeting; and to provide instructions on the review and approval of study activities using the Emergency Meeting Procedures

2. Scope

This SOP applies to emergency Institutional Ethics Committee (IEC) meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Board review.

3. Responsibility

The IEC Chairperson may call for an emergency meeting as appropriate.

4. Flow chart

No.	Activity	Responsibility
1	Before the Board meeting	IEC Secretariat
2	During the meeting	IEC Members and Chairperson
3	After the meeting	IEC Secretariat

5. Detailed instructions

5.1 Before the Board meeting

5.1.1 The Chairperson/ Member Secretary will decide to call an emergency meeting for any one or more of the following reasons:

- Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
- Occurrence of unexpected serious adverse event(s).
- A matter of life and death for the patients continuing in the trial.
- Other reasons, as deemed appropriate by the Chairperson.

5.1.2 Contact and inform IEC members

- The Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The Secretariat/ Administrative Officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which Emergency Meeting is scheduled or send the relevant details (incase the documents are too many) via email.

- The Administrative Officer will attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendance confirmation form to the packets.
- The Administrative Officer will refer to and act according to the relevant SOPs depending upon the matter under consideration.

5.2 During the meeting

- The Chairperson/Secretary will determine if there is a quorum.
- If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes; the meeting would be held without a quorum provided at least three members (other than Chairperson and including at least one scientific member) are present, given the urgency of the matter under consideration. The IEC member will follow the related SOPs as deemed necessary.
  - SOP 02/V1 - Constituting Ethics Committee for Research on Human Subjects.
  - SOP 05/V1 - Management of Protocol Submissions.
  - SOP 06/V1 - Initial Review of Submitted Protocol.
  - SOP 07/V1 - Expedited Review.
  - SOP 09/V1 - Review of Amended Protocol/Protocol related documents.
  - SOP 10/V1 - Continuing Review of Study Protocols.
  - SOP 16/V1 - Agenda Preparation, Meeting procedures and recording of minutes.
  - SOP 14/V1 - Review of SAE.
  - SOP 12/V1- Review of protocol deviations/violations

5.3 After the meeting

- The Secretariat will follow the related SOPs as listed in 5.2.

6. Glossary

Emergency meeting	An IEC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IEC review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion. Emergency meetings may be held via teleconference, if applicable.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

Title: Maintenance of Active Project Files

SOP Code: SOP 18/V1 dated 22nd August 2016

Authors:

Dr. RAHUL PRAKASH BHAVASAR (Member IEC) 01/09/2016

Reviewed by:

Dr. DEVENDRA R. CHAUDHARI (Member Secretary) 01/09/2016

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson IEC
(Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	4

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to all active study files and their related documents that are maintained in the IEC office.

3. Responsibility

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. Flow chart

No.	Activity	Responsibility
1	Organize the contents of the active study files	IEC Secretariat
2	Maintain the active study files	IEC Secretariat

5. Detailed instructions

5.1 Organize the contents of the active study files

The Secretariat will:

- Preserve one original set (hard copy and soft copy) of the entire file (called as master file) and rest of the five sets will be shredded following the IEC meeting in which the initial review of a study is done.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original application form with the initial protocol submitted for initial review and any updates received (containing the entire list as mentioned in SOP 09/01 Procedures for Review of Amended protocol/Protocol related documents).
  - Investigator's brochures or similar documents.
  - Agreements signed by appropriate authorities, including Clinical trial agreement, Insurance document.
  - Photocopies of statutory permissions, as applicable.

- Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
- Approval letters for protocol & protocol related documents.
- Adverse event reports, IND safety reports received and/ or SAE reports.
- Continuing review reports.
- A copy of every original letter/ communication received from the Principal Investigator.
- A copy of every letter/ communication sent to the investigator.

- The Administrative Officer will use a folder for each study file and affix an identity label on the folder cover:
  - The name of the sponsor/Principal Investigator.
  - The protocol number assigned by the IEC Secretariat.
- The Administrative Officer will put the following documents into each folder with the following information:
  - Sponsor details: Name with address and contact phone/ e-mail id of contact person, protocol number.
  - Investigator name (with address, e-mail, telephone and fax) and title of the study.
  - IEC Application form duly filled in and signed by the investigator at the time of initial submission.
  - Initial and various versions of the Protocol, Case Record Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator.
  - Correspondence with the investigator.
  - Initial Approval with the final version of all above documents. (Protocol, ICD, CRF etc.)
  - Revisions/Amendments.
  - Approval of amended protocol/protocol related documents.
  - Protocol deviations / violations
  - Hard copies of Adverse Events and SAEs at this site,
  - Soft copy (CD) of SAEs at other site/s, CIOMS, SUSAR, Appendix XI reports and Safety reports
  - Continuing Review, if applicable.
  - Final report.

For studies with multiple study sites, the Administrative Officer should maintain the files with sub-folders to allow easy cross-referencing without unnecessary duplications.

5.2 Maintain the active study files

The Administrative Officer will:

- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.
- Keep all active and potential study packages in a secure place.
- Maintain the study files in an easily accessible, but secure place until the final report is received, reviewed and accepted by the IEC or the matter will be discussed at Full Board by IEC.
- Send all closed study files to the archive.

6. Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Master file	A file for storage of the originally signed and dated documents

Title: Archiving and Retrieving Documents

SOP Code: SOP 19/V1 dated 22nd August 2016

Authors:

Dr. MAYA ARVIKAR (Member IEC) 1/9/2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016 Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2

6	Glossary	4
7	References	4
8	Annexure	4

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors, inspectors and other authorized persons.

2. Scope

This SOP applies to archiving the study files and administrative documents that are retained for at least five years or for longer duration if specifically mandated after completion of the research/ termination of research so that the records are accessible to auditors, inspectors and other authorized persons. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of the Institutional Ethics Committee (IEC) Secretariat to maintain inactive study files and administrative documents.

4. Flow chart

No.	Activity	Responsibility
1	After receiving the final report	IEC members, secretariat
2	Retrieving Documents	IEC secretariat

5. Detailed instructions:

5.1 After receiving the final report and/ or terminating the study:

- IEC Secretariat and Members will review the Final Report of the study.
- A member of the Secretariat should:
  - Remove the contents of the entire file from the active study filing area.
  - Verify that all documents are present in an organized manner.
  - Shift it to a cupboard where in files to be archived are placed.
- The Secretariat/ Administrative Officer will place the files in the cupboard at a given area together.

- A staff of the IEC Secretariat should
  - Perform inventories of miscellaneous administrative documents.
  - Send it/ them to the appropriate storage facility so that it/ they may be retrieved.
- The IEC Secretariat maintains past board membership information as well as the active administrative documents as permanent records.

5.2 Retrieving Documents

- The Secretariat will keep in mind the SOP 20/V1 (Maintaining Confidentiality of IEC Documents)
- The request for retrieval can only be made by an IEC member, auditor or other authorized person in by filling up, signing and dating request form: *AX 01/SOP 19/V1*
- The requestor must also sign and date the log of request. *(AX 02/SOP 19/V1)*
- Retrieval of documents can only be done when a request is made in the request form (*AX 01/SOP 19/V1)* that is approved (signed and dated) by the IEC Chairperson/Member Secretary.
- For administrative purpose and while discussing / keeping the study completion report , IEC Secretary can retrieve archived file(s) without having to require IEC Chairperson's approval. For this purpose the IEC secretary can authorize a staff member of the IEC secretariat to physically retrieve a file. In such a situation, the register/ log will be signed by the secretariat member physically retrieving the file.
- A member of IEC Secretariat will retrieve archived document(s) and will return the remaining file back to its place.
- The Secretariat maintains a register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC chairperson, Date and time of retrieval, Name and signature of IEC staff/ Secretariat retrieving the file, Date and time of returning the file.
- The Secretariat will also record, sign and date when the document has been returned and kept.

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings and the Standard Operating Procedures, both historical files and Master Files as.
Inactive Study Files	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to research participants, scientific evaluations) that correspond to each study approved by the *IEC* Board for which a final report has been reviewed and accepted.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 31st August 2016).

8. Annexure

Annexure 1 *AX 01/SOP 19/V1* Document Request Form

Annexure 2 *AX 02/SOP 19/V1* Log of Requested IEC Documents

Annexure 1

AX 01/SOP 19/V1

Document Request Form

Name of Document requested:		
Requested by: Name: ----------		
☐ Chairperson	☐ Secretariat	☐ IEC Member
☐ Secretariat staff	☐ Authority	☐ Others _____

Purpose of the request:

Signature of person requesting and date

Signature of Member Secretary/ Chairperson and date

Annexure 2

AX 02/SOP 19/V1

Log of requested IEC Documents

No	File Number and Document	Name and Designation of person requesting with his/her signature	Date Requested	Date of approval	Retrieved by (Name, Signature and Date)	Returned Date	Archived by (Name, Signature and Date)

Title: Maintaining Confidentiality of IEC Documents

SOP Code: **SOP 20/V1 dated 22nd August 2016**

Authors:

Dr. RAHUL PRAKASH BHAVASAR (Member, IEC) 01.09.2016

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	4
7	References	5
8	Annexure	5

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the handling of original documents, their copies and communications received from and sent to investigators, regulators, sponsors, etc. in order to protect confidentiality of documents.

2. Scope

This SOP applies to the handling, distribution and storage of submitted study protocols and other documents, the Institutional Ethics Committee (IEC) documents, and correspondence with experts, auditors and the general public.

3. Responsibility

Maintaining the confidentiality of study protocols and documents, IEC documents, and correspondence with experts and auditors is mandatory. IEC members and staff, Guest attendees or observers and independent consultants who have signed confidentiality agreement(s) have to ensure and enforce confidentiality.

If an IEC member/ staff requests for a copy of one of the documents listed above on behalf of a non-member, it is the responsibility of the IEC member/staff to maintain confidentiality of documents.

4. Flow chart

No.	Activity	Responsibility
1	Access to IEC documents	IEC members and Secretariat
2	Classify confidential documents	IEC members and Secretariat
3	Copy confidential documents	IEC Secretariat
4	File Log of Copies	IEC Secretariat

5. Detailed instructions

5.1 Access to IEC Documents

Only IEC members and staff of the IEC Secretariat have access to the hard copy / soft copy of the study documents, IEC documents, IEC communications and letters and communications received from investigators, regulators, sponsors and other individuals/organizations concerned with study or research. They will have access only after they have read, understood, agreed upon and signed the Confidentiality Agreement.

5.1.1 Members of the IEC

- Each and every IEC member must sign a confidentiality agreement (*AX 01/SOP 03/V1*) before the start of a new tenure of IEC or IEC membership.
- Any member who is appointed during an ongoing term of the IEC is required to sign the Confidentiality Agreement before he/ she has access to any confidential material.

The IEC members shall have access to all IEC documents and are free to request and to use original documents or copies of original documents.

5.1.2 Secretariat of the IEC

- The Secretariat of the IEC is a staff member of the IEC.
- The member must sign a confidentiality agreement with IEC before he/ she has access to any of the IEC documents.
- The staff member will have access to any document issued by or to the IEC according to SOP 20/V1 (Maintaining Confidentiality of IEC Documents).

5.2 Classify confidential documents.

The types of documents reviewed by IEC members include:

- Study protocols and related documents (including case record forms, informed consent documents, diary forms, scientific documents, expert opinions, reviews, etc.)
- IEC documents (SOPs, meeting agenda and minutes, advice and decisions, periodic reports, audit reports, etc.)
- Correspondence (with experts, auditors, study participants, regulators, etc.)

Note: Copies of all versions of documents, including draft and sequential definitive versions are to be kept private and confidential with the exception of those made according to the following sections.

5.3 Copy confidential documents

Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out except when a document is needed for day-to-day operations.

5.3.1 Copy Authorization

- Only members of the IEC can request the Member Secretary IEC for copies of documents without having to take an express permission from the IEC Chairperson, provided the document is related to an active file/ project.
- Only staff members of the Secretariat of the IEC are allowed to make such copies.
- The overall responsibility of maintaining confidentiality of documents rests with the Secretary of the IEC. However, he/ she can be assisted by authorized staff members of the secretariat or IEC members in this regard.

5.3.2. Log of Copies

- A Log of Copies (*AX 01/SOP 20/V1*) must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the IEC Secretary who made the copy; the number of copies made and the date that the copies were made.

5.4. Copies requested by non-members of the IEC

- A non-member can request the Chairperson/ Member Secretary of the IEC in writing for a copy of an IEC document citing specific reason(s).
- Copies of IEC documents requested by non-members of the IEC can only be given after the permission from the Chairperson/ Member Secretary of the IEC if the request is found to be reasonable and the person requesting for the document signs a confidentiality agreement form (*AX 03/SOP 03/V1*). If deemed necessary by the Chairperson/ Member Secretary, the letter of request may be discussed at the forthcoming full board meeting for final decision.
- Copies made for non-members of the IEC must be recorded in both the Log of Requests for Copies of IEC documents (*AX 01/SOP 20/V1*) and the log of Copies of the Original Documents (*AX 02/SOP 20/V1*).

5.4 File Log of Copies.

- The Log of Copies of Original Documents must be stored with the original documents. It is not necessary to maintain log of copies when IEC member has requested for them.
- The Log of Copies of Original Documents is *not* a confidential document and can be reviewed upon request.
- A Log of Copies of Original Documents must be maintained.

6. Glossary

Document	Documents mean the following: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC documents (SOPs, meeting minutes, advice and decisions) - Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Non-members of the IEC	Any person/persons/ organizations who/ that presently is/are not a member/members of the IEC such as administrative authorities, monitors, auditors, research participants, regulators, insurance agencies, etc.

7. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

8. Annexure

Annexure 1 *AX 01/SOP 20/V1* Log of Requests for Copies of IEC Documents

Annexure 2 *AX 02/SOP 20/V1* Log of Copies of Original Documents

Annexure 1

AX 01/SOP 20/V1

Log of Requests for Copies of IEC Documents

No./ date of request	Documents requested (including file number if relevant	No. of Copies	Name of the individual requesting for copy/ copies	Reason for request	Signature of the individual receiving the copy and date	Name and Signature of the IEC staff providing the copy and date

Annexure 2

AX 02/SOP 20/V1

Log of Copies of Original Documents

Title of the Document: _____

No	Name of Recipient	No. of Copies	Reasons of the Request	Signature of Recipient and date	Secretariat Name Initials and date

Note: This log should be attached to the original documents.

Title: Responding to Research Participant's Request or Complaint

SOP Code: SOP 21/V1 dated 22nd August 2016

Authors:

Dr. Nilesh Bendale, (Member, IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Filing the request documents	4
7	References	4
8	Annexure	4

1. Purpose

The Institutional Ethics Committee (IEC) considers protection of the rights and welfare of the human subjects participating in a clinical investigation/ research approved by it, as its primary responsibility.

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with requests by research participants/ patients regarding their rights as a participant or to resolve their complaint(s) that is/ are related to their participation in research/ trial approved by *IEC*.

2. Scope:

This SOP applies to all requests/ complaints concerning the rights and well-being of the research participants participating in studies approved by the IEC.

3. Responsibility:

It is the responsibility of the *IEC* Secretariat for providing required information to the research participants in case of queries received from research participants.

It is the responsibility of the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred if complaints are received from research participants.

4. Flow chart

No.	Activity	Responsibility
1.	Receiving the query/complaint from research participant	*IEC* Chairperson/ Secretariat/ Members
2.	Providing information to research participant	*IEC* Chairperson/ Secretariat/ Members
3.	Initiating process to identify the problem	*IEC* Chairperson
4.	Deliberations to arrive at solution	*IEC* Chairperson/ Secretariat/ Members
5.	Communication with the research participant	*IEC* Secretariat
6.	File the request document	*IEC* Secretariat Administrative staff

5. Detailed instructions:

- After receiving a request, complaint or query, the *IEC* member or administrative staff will record it in the request record form *AX 01/SOP 21/V1*. The *IEC* member will forward the request to the Secretariat.

- The Secretary will ascertain if the concerned individual has been approached to participate in the study or is already participating in the study based on documents available with. If required, the IEC will call for relevant information and documents from the Investigator, as required
- The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification:

  The Chairperson will decide to provide the information himself / herself or will designate one or more *IEC* member to provide such information. The Secretariat will make all documents relevant to the request, available to the Chairperson/ designated member.

- In case of complaint received from a research participant, the Chairperson initiates a process to identify and address any injustice that may have occurred. The Chairperson will direct the Member Secretary to:

  - Consider the matter for discussion at the next full board meeting or call an emergency meeting of two or more *IEC* members for discussion or appoint a subcommittee of two or more *IEC* members for enquiry in order to resolve the matter.
  - The Chairperson/ Member Secretary/ designated *IEC* members will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.
  - The *IEC* will insist on factual details to determine gap, if any, between truth and individual perception.
  - The final decision will be taken by the Chairperson based on any one or a combination of processes listed below:

    a) Discussions at the Full-Board meeting

    b) Discussions at the meeting of selected/ designated *IEC* members

    c) Report provided by the subcommittee appointed by the Chairperson

- The final decision will be informed to the research participant by the Secretariat.
- The information including any action taken or follow-up will be recorded in the form *AX 01/SOP 21/V1* and the form is signed and dated.
- The *IEC* members are informed about the action taken and the outcomes in the forthcoming *IEC* meeting.

6. Filing the request document

The Secretariat staff/ Secretary will place the request record form in the relevant study file.

7. Reference

Kathleen J. Motil, Janet Allen and Addison Taylor, "When a Research Subject Calls with a Complaint, What Will the Institutional Ethics Committee do?" *IEC: Ethics and Human Research* 26, no.1 (January –February 2004):9-13

8. Annexure

Annexure 1 *AX 01/SOP 21/V1* Request Record Form

Annexure 1

AX 01/SOP 21/V1

Request Record Form

Date	
Received by :	
Request received through:	❑ Telephone call No _____ ❑ Fax No _____ ❑ Letter / Date _____ ❑ E-mail / Date _____ ❑ Walk-in / Date / Time _____ ❑ Other, specify _____
Participant's Name:	
Contact Address: **Phone:**	

Title of the Participating Study	
Starting date of participation :	
Information requested/ complaint/query	
Action taken: **Outcome:**	

_____

Signature of the IEC Chairperson

Date _____

Institutional Ethics Committee (IEC)
Dr. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Title: Exemption from the Ethics Review for Research Projects

SOP Code: SOP 22/V1 dated 22nd August 2016

Authors:

Dr. Nilesh Bendale, (Member, IEC)

Reviewed by:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	3
7	References	4
8	Annexure	4

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe which clinical research projects can be exempted from ethics review and do not require the approval of the Ethics Committee Research on Human Subjects (IEC). The Exemption Form *AX 01/SOP 22/V1* is designed to standardize the process of exemption.

2. Scope

This SOP applies to the all protocols submitted for exemption from review by the IEC. The specific points in the Exemption Form should guide the Member Secretary to determine whether the protocol qualifies for exemption from review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the Members in the forthcoming IEC meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson must sign and date letter conveying the decision *AX 01/SOP 22/V1*.

4. Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Review of protocol and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairperson	Member Secretary
4	Communicate the decision to the Investigator	IEC Secretariat
5	Informing the decision to the members in the forthcoming meeting	Member Secretary
6	Recording and filing the decision	IEC Secretariat

5. Detailed instructions

5.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form *AX 01/SOP 22/V1*, Protocol and other documents submitted by the investigators.
- The Administrative Officer will sign his/her name on the receiving documents.

5.2 Determine protocols eligible for exemption from review

The IEC Member Secretary will determine whether a protocol qualifies for exemption from review based on the following criteria. Final decision will be made by the Chairperson.

The research proposals which do not involve live human participants or data derived from them are exempt from ethics review. For example,

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- ✓ The publisher of the research
- ✓ An organization which is providing funding resources, existing data, access to participants etc.

5.3 Exemption Process

- If the protocol and related documents satisfy the criteria as listed in 5.2, the Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.
- The Member Secretary records the decision on the Exemption Form
- The Secretariat communicates the decision to the investigator.
- The Member Secretary informs the IEC members about the decision at the next full board meeting.
- The Member Secretary / Chairperson may keep the application for review and decision regarding exemption at the next full board meeting.

5.4 Communication

- The decision regarding request for Exemption from review, signed by the IEC Chairperson, will be forwarded by the Secretariat to the Principal Investigator within 14 days after the decision regarding the exemption is taken.
- The Member Secretary will inform the IEC members of the decision at the forthcoming regular meeting and minute it in the meeting notes.

6. Glossary

Exemption from review	A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct

7. References

[1] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - *http://www.icmr.nic.in/ethicalguidelines.pdf* (last accessed 31st August 20103)

8. Annexure

Annexure 1 *AX 01/SOP 22/V1* Review exemption application form

Annexure 1

AX 01/SOP 22/V1

Review Exemption Application Form

1 **Principal Investigator's Name:** _____

2 **Department:** _____

3 **Title of Project:** _____

_____

_____

4 **Names of other participating staff and students:**

_____

_____

5 **Brief description of the project:**

Please give a brief summary (approx. 300 words) of the nature of the proposal, including the aims/objectives/hypotheses of the project, rationale, participants' description, and procedures/methods to be used in the project:-

6 **State reasons why exemption from ethics review is requested?**

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain
- ✓ Any other

(This should include justification for exemption e.g. study does not involve human participants. If exemption is being requested on the basis of low risk involved in the study please refer to the backside of this annexure.)

Institutional Ethics Committee (IEC)
Dr. Ulhas Patil Medical College & Hospital Jalgaon kh - 425309.

Principal Investigator's signature: _____ **Date** _____

Forwarded by the Head of the department:

Name: _____ **Signature:** _____ **Date**_____

Recommendations by the IEC Member Secretary:

Exemption

Can not be exempted, Reasons_____

Discussion at full board

Signature of the Member Secretary: _____ **Date** _____

Final Decision:

Exemption

Can not be exempted,

Reasons_____

Discussion at full board

Signature of the Chairperson: _____ **Date** _____

Final Decision at Full Board meeting held on _____

_____

_____

Signature of the Chairperson: _____ **Date** _____

No research can be counted as low risk if it involves:

(i) Invasive physical procedures or potential for physical harm

(ii) Procedures which might cause mental/emotional stress or distress, moral or cultural offence

(iii) Personal or sensitive issues

(iv) Vulnerable groups

(v) Cross cultural research

(vi) Investigation of illegal behaviour(s)

(vii) Invasion of privacy

(viii) Collection of information that might be disadvantageous to the participant

(ix) Use of information already collected that is not in the public arena which might be disadvantageous to the participant

(x) Use of information already collected which was collected under agreement of confidentiality

(xi) Participants who are unable to give informed consent

(xii) Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment-provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

(xiii) Deception

(xiv) Audio or visual recording without consent

(xv) Withholding benefits from "control" groups

(xvi) Inducements

(xvii) Risks to the researcher

This list is not definitive but is intended to sensitize the researcher to the types of issues to be considered. Low risk research would involve the same risk as might be encountered in normal daily life. Please check that your application / summary has discussed:

- Procedures for voluntary, informed consent
- Privacy & confidentiality
- Risk to participants
- Needs of dependent persons
- Conflict of interest
- Permission for access to participants from other institutions or bodies
- Inducements

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research
- An organisation which is providing funding resources, existing data, access to participants etc.

Title: Request for Waiver of Written Informed Consent

SOP Code: **SOP 23/V1 dated 22nd August 2016**

Authors:

Dr. Devendra R. Chaudhari, (Member Secretary, IEC) 01/09/16

Reviewed by:

Dr. RAHUL PRAKASH BHAVASAR ,(Member, IEC) 01.09.2016

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	References	3
7	Annexure	3

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Review Board (IEC) may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent. The Application Form *AX 01/SOP 23/V1* is designed to standardize the process of applying for consent waiver.

2. Scope

This SOP applies to the all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members at the Full Board meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Application Form. The Chairperson must sign and date letter conveying the decision *AX 01/SOP 23/V1.*

4. Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Review of protocol and application for waiver of consent	IEC Members
3	Decision regarding waiver of consent	IEC Members at Full Board meeting
4	Communicate the decision to the Investigator	IEC Secretariat
5	Recording and filing the decision	IEC Secretariat

5. Detailed instructions

- When a request for waiver of consent is submitted by the Principal Investigator to the IEC secretariat, in the given format *AX 01/SOP 23/V1* stating the reasons for the consent waiver; the following steps are taken:

  ✓ The IEC Secretariat will check if the concerned documents are filled completely and the required list of documents is enclosed.

  ✓ The IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. (Criteria stated on the back of the annexure *AX 01/SOP 23/V1).*

  ✓ The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.

✓ The decision whether to grant the waiver is taken at a full board meeting.

✓ The decision regarding approval/disapproval of waiver is informed to the principal investigator in writing. If the waiver is not granted, the IEC will provide reasons for the same.

6. References:

[1] Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st August 2016).

[2] 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm, paragraph 46.116- 'General Requirements for Informed Consent' (last accessed on 31st August 2016).

7. Annexure

Annexure 1 *AX 01/SOP 23/V1* Application form for requesting waiver of consent

Annexure

AX 01/SOP 23/V1

Application form for requesting waiver of consent

1. **Principal Investigator's name:** _____
2. **Department:** _____
3. **Title of project:**

_____

_____

_____

4. **Names of other participants, staffs and students:**

_____

_____

_____

5. **Request for waiver of informed consent:**

- Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

[1] Research involves 'not more than minimal risk'

[2] There is no direct contact between the researcher and participant

[3] Emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)

[4] Any other (please specify)

_____

- Statement assuring that the rights of the participants are not violated

_____

- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

_____

Principal Investigator's signature with date: _____

Final decision at full board meeting held on: _____

Waiver granted Yes ☐ No. ☐

If not granted, reasons _____

_____

_____

Signature of the Chairperson with Date: _____

Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2006 guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. (*ICMR guidelines*, 45CFR 46*)* e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].
2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. *(ICMR 2006 guidelines)*

   e.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.

   The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC.

   [In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].

   The following points need to be considered.

   a. The following documents need to be submitted for the IEC review

      - A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.

- The interview schedule (questions to be asked???) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.

b. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the paticipants as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2006 guidelines)

4. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. (ICMR 2006 guidelines)

5. In emergency situations when no surrogate consent can be taken. *(ICMR 2006 guidelines)* when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

References:

[1] Ethical Guidelines for Biomedical research on Human Participants, ICMR 2006 http://www.icmr.nic.in/ethical_guidelines.pdf.

[2] 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm, paragraph 46.116- 'General Requirements for Informed Consent'.

Title: Reviewing proposals involving vulnerable Populations.

SOP Code: SOP 24/V1 dated 22nd August 2016

Authors: DR. DEVENDRA R. CHAUDHARI (MEMBER SECRETORY IEC) 01/09/16

Reviewed by: DR. RAHUL PRAKSH BHAVASAR. (MEMBER, IEC) 01.09.2

Approved by:

01/09/2016
Dr. Ravinadrakumar Bakal, Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	1
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	4
7	References	5
8	Annexure	6

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous

instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

2. Scope

This SOP covers the policies and procedures applied to all research dealing with vulnerable population submitted to the IEC.

3. Responsibility

- It is the responsibility of the Secretariat of IEC to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
- IEC Chairperson/ Member Secretary is responsible for ensuring that IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.
- IEC member is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP

3.1 Secretariat of the Institutional Review Board will

- Maintain on file the update checklist (A-F) which conforms to applicable regulations and guidelines.
- Document review of risk assessment in IEC minutes for the protocols involving vulnerable population.
- Confirm that the complete informed consent and assent documents as relevant.

3.2 Chairperson / Member Secretary will:

Select appropriate primary reviewer(s).

3.3 IEC members will:

- Complete checklist during review of research with vulnerable populations and present recommendations at the convened meeting.

4. Flow Chart

No.	Activity	Responsibility
1	Reviewing the protocol with vulnerable population	Any member of IEC and designated reviewer, secretariat or administrative staff
2	Appoint one or more reviewers	Chairperson/ Member Secretary
3	Review the protocol	IEC members

5. Detailed instructions

5.1 Reviewing the protocol with vulnerable population

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchical society.

The protocol should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion

- measure to protect autonomy,
- risk/benefit determinations with respect to the vulnerability
- bearing unequal burden in research.

Any member of the IEC or Secretariat who would be dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable population is being provided in Annexure (A-F). Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

5.2 Appoint the Reviewers

The Chairperson will appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

5.3 Secretariat duties

- Provide a suitable checklist according to the subjects to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/ assent form.
- Provide appropriate reference material or help reviewer locate such material related to vulnerable populations when specifically requested for, by a reviewing member

5.4 Reviewers responsibility

- IEC Members will review the protocol and the informed consent document or assent form.
- The reviewers comments will be discussed in the IEC meeting and the final comments will be sent to the PI.
- The discussion will be documented in the minutes.
- The member secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.

5.5 Approval of the protocol

- The final version of the protocol will be approved by the board with the appropriate checklist as given in annexure (1-5).
- Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and approval Following which the participant should be re-consented and reconsidered for the same.

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.
IEC members	Individuals serving as regular members of the Institutional Review Board. The Committee has been constituted in accordance with the EC membership requirements set forth in Schedule Y (20th January 2005)
Vulnerable population	Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.
Children	Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
Assent	Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
	Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any

Pregnant women	of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
Fetus	Fetus means the product of conception from implantation until delivery.
Viable fetus	Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
Non viable fetus	Nonviable neonate means a neonate after delivery that, although living, is not viable.
Neonate	Neonate means a newborn.
Mentally impaired persons	Mentally incapable to give consent due to the situation /condition
Situational vulnerability	Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities,
Harm	is a negative safety or health consequence; any detrimental effect of a significant nature
Risk	"chance"/probability that harm can occur

7. References

1] Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (Geneva 2011) - www.who.int/...guideline.../operational-guidelines-ethics-biomedical-... (last accessed 31st August 2016)

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996. http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st August 2016)

[3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st August 2016)

[4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm (last accessed 31st August 2016)

[5] Council for International Organizations of Medical Sciences (CIOMS) Guidelines www.cioms.ch/publications/layout_guide2002.pdf (last accessed 31st August 2016)

[6] Good Clinical Practices for Clinical Research in India http://cdsco.nic.in/html/GCP.htm (last accessed 31st August 2016)

[7] World Medical Association Declaration of Helsinki, http:// www.wma.net/en/30publications/10policies/b3/ (last accessed 31st August 2016)

[8] ICMR-DBT Guidelines for Stem Cell Research 2012 (Draft) icmr.nic.in/stem_cell_guidelines.pdf (last accessed 31st August 2016)

[9]http://www.mmcri.org/home/webSubContent.php?subCatID=4&catID=2&headType=IEC&catLevel=subCat (last accessed 31st August 2016)

8. Annexure

Annexure 1	*AX 01/SOP 24/V1*	Checklist – Requirements for Research Involving Children
Annexure 2	AX 02/SOP 24/V1	Checklist – Requirements for Research Involving Pregnant Women & Fetuses
Annexure 3	AX 03/SOP 24/V1	Checklist- Research Involving Cognitively Impaired Adults
Annexure 4	AX 04/SOP 24/V1	Checklist-Research Involving Students, Employees or Residents
Annexure 5	AX 05/SOP 24/V1	Checklist- Considerations for Genetic Research

Annexure 1

AX 01/SOP 24/V1

Checklist –Requirements for Research Involving Children

Investigator: _____ IEC :

Study Title: _____

For the principal investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
Minimal *	☐ Direct benefit	Approvable
	☐ No direct benefit	
Greater than minimal risk	☐ Potential to child	Approvable
Greater than minimal risk	☐ No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by-case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honouring their dissent?			
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counselling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a. which has implications for other family member ?(for example, genetic risk , HIV infection , Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents be required to be present during the conduct of the research? (Are proposed subjects to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)			

- Approval to proceed with this category of research must be made by the Administrator of the IEC, with input from selected experts

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 2

AX 02/SOP 24/V1

Checklist – Requirements for Research Involving Pregnant Women & Fetuses

Investigator: ***IEC #:***

Study Title:

SECTION 1

THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY

	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;			
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived.			

The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and			
Individuals engaged in the research will have no part in determining the viability of a fetus.			

If the response to any of the above is No, the research is not approvable by the IEC at this time. See section 3

SECTION 2
THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY

	Yes	No	NA
1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
2. The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus or resultant child;			
3. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
4. Individuals engaged in the **research** will have no part in any decisions as to the timing, method, or procedures used to terminate pregnancy;			
5. Individuals engaged in the **research** will have no part in determining the viability of a fetus.			

AND

A. Fetuses of uncertain viability	**Yes**	**No**	**NA**
1. Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research**;			
OR			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;			

2. The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

And/or

B. Nonviable fetuses	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;			
2. There will be no risk to the fetus resulting from the research;			
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
4. The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.			

If the response to any of above is **No,** the research is not approvable by the IEC at this time. See section 3.

SECTION 3

THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IEC finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses **and,**

(b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) to determine either:

(1) That the research in fact satisfies the conditions of Schedule Y , as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses;

(ii) The research will be conducted in accord in sound ethical principles; and

(iii) Informed consent will be obtained in accord with informed consent provisions of Schedule Y and other applicable subparts, unless altered or waived in accord.

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 3

AX 03/SOP 24/V1

Checklist- Research Involving Cognitively Impaired Adults

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
  1. For review using the expedited procedure this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
  2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")		
Yes	No	One of the following is true (Check the box t-hat is true) The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. More than minimal risk to subjects is

		presented by monitoring procedure that is likely to contribute to the subjects well – being.
Yes	No	The risk is justified by the anticipated benefit to the subjects.
Yes	No	The relation of anticipated benefit to the risk is at least as favourable to the subjects as that presented by available alternative approaches.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of: (One of the following must be **"Yes"**) One of the following is true **(Check box that is true)** All Subjects All Subjects capable of being consulted. None of the subjects
Yes	No	The consent document includes a signature line for a legally authorized representative.

2.Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	The objectives of the trial cannot be met by means of study of subjects who can give consent personally.
Yes	No	The foreseeable risks to the subjects are low.
Yes	No	The negative impact on the subject's well-being is minimized and low.

Yes	No	The trial is not prohibited by law.
Yes	No	Subjects have a disease or condition for which the procedures in the research are intended.
Yes	No	Subjects will be particularly closely monitored.
Yes	No	Subjects will be withdrawn if they appear to be unduly distressed.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of (One of the following must be **"Yes"**) One of the following is true **(Check box that is true)** All Subjects All Subjects capable of being consulted. None of the subjects
Yes	No	The consent document includes a signature line for a legally authorized representative.

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 4

AX 04/SOP01/V1

Checklist-Research Involving Students, Employees or Residents

Subjects who are students, employees or residents require special considerations.

Does the employer or supervisor of the research subject need to be aware of the research project?	No	Yes
Is there a letter of support and/ or internal services checklist?	No	Yes

Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to subjects been minimized?	No	Yes
Have subjects been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have subjects been assured that confidentiality will be protected or maintained?	No	Yes

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 5

AX 05/SOP 24/V1

Checklist - Considerations for Genetic Research

Investigator: ***IEC #***

Study Title:

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
2. Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
3. Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?		
4. Does the proposed study population comprise family members?		
5. Will family members be implicated in the studies without consent?		
6. Will the samples be destroyed in the future?		
7. Is genetic counseling being offered?		

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Title: Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)

SOP Code: SOP 01/V1 dated 22nd August 2016

Authors:

Dr. Devendra R. Chaudhari (Member Secretary, IEC) 01/09/16

Reviewed by:

Dr. Rahul Prakash Bhavasar (Member, IEC) 01.09.2016

Approved by:

01/09/2016

Dr. Ravindrakumar Bakal , Chairperson, IEC (Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	3
5	Detailed Instructions	3
6	Glossary	5
7	References	6
8	Annexure	6

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), Dr. Ulhas Patil Medical College and Hospital, Jalgaon kh. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant, National and International Guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Institutional Ethics Committee (IEC).

3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint the SOP Team to formulate the SOPs. The SOP Team shall do this by following the same procedures, format, and coding system when drafting or editing any SOP of the Institutional Ethics Committee.

3.1 Secretariat of the Institutional Ethics Committee will

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the IEC members.
- Maintain a record of the investigators to whom SOPs are distributed
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain on file all past SOPs of the IEC
- Assist Chairperson to formulate an SOP Team

3.2 SOP team (will contain Member Secretary and at least two other members) will:

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

3.3 Chairperson of the IEC will:

- Appoint one or more SOP Teams
- Approve the SOPs
- Sign and date the approved SOPs

3.4 IEC members and involved administrative staff will:

- Sign and date the approved SOP when they receive it
- Maintain a file of all SOPs received

4. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amending SOP	Any member of IEC, secretariat or administrative staff
2	Appoint one or more SOP Teams	Chairperson
3	List all relevant SOPs	SOP Team
4	Design a format and layout	SOP Team
5	Write and review a new/revised SOP	SOP Team
7	Preparation and submission of final draft	SOP Team
8	Approve a new/revised SOP	Chairperson
9	Ensure implementation, distribute and file all SOPs	IEC members and Secretariat
10	Review and request for a revision of existing SOPs	IEC members/ Administrative staff/ Chairperson
11	Manage current and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Identify the need for new or amending SOP

Any member of the IEC or Secretariat who would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by using the Request for Formulation of new SOP/ Revision of an SOP Form *AX 05/SOP01/V1* to make a request. This annexure form is submitted to the IEC Chairperson.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairperson will inform the person/ IEC member who made the request for modification of the SOP will be informed in writing about the decision.

5.2 Appoint the SOP Team(s)

The Chairperson will constitute an SOP Committee(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review process. The SOP writing team will carry out the subsequent steps. (5.3-5.7)

5.3 List all relevant SOPs

- Write down step by step all the procedures of the Institutional Ethics Committee

- Organize, divide and name each process

5.4 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format **SOP xx/Vy** will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version. The current version of the SOPs would be the **third one** hence it will be denoted as "V1". The first SOP of the current version would be SOP 01/V1 i.e. it is SOP number 01 with version 3.

Each annexure will be given unique code number with the format ***AX pp/SOP xx/Vy***. AX refers to annexure form, *pp* is a two-digit number identifying the number of the annexure, while *xx/Vy* refers to the SOP number and its version. For example *AX 01/SOP01/V1* means annexure form number one belonging to the SOP 01/V1.

Each SOP will be prepared according to the standard template in *AX 02/SOP01/V1*. Each page of the SOP will bear the header which will have the effective date i.e. the date of approval of the SOPs. The SOP number will be on the left hand corner while the right hand corner will bear the page number as Page - of total pages. The first page of each SOP document will be signed and dated by the authors, the IEC members who have reviewed the SOPs and the IEC Chairperson and subsequently the SOP will be implemented from that date.

5.5 Write and review a new/revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form *AX 03/SOP01/V1* along with description of the main changes.
- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.

5.6 Review by Consultation

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by the SOP team members; a copy of the revised draft SOP will be sent to the Member-Secretary, who will circulate it to all the IEC members.

5.7 Preparation and submission of final draft

- IEC Members will review the revised draft SOP at a special meeting.
- The suggestions that are agreed upon by the IEC members present at the special meeting will be discussed and incorporated in the revised draft SOP and the final draft of the SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

File No. EC/21/000320

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 18-Nov-2021

To
The Chairman
Institutional Ethics Committee
Dr. Ulhas Patil Medical College and Hospital,
1St Floor, College Building, DUPMCH
Jalgaon- 425309, Maharashtra, India

Subject: Ethics Committee Re-Registration No. ECR/852/Inst/MH/2016/RR-21 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2021/12770 dated 09-Oct-2021 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/852/Inst/MH/2016/RR-21. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 18-Nov-2021 to 17-Nov-2026, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or

ethicist or theologian or a similar person;
(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre: Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

File No. EC/21/000320

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 18-Nov-2021

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. Satish Govindrao Gadage	LLB (Master of Laws (LL.M.))	Legal Expert
2	Dr. Parag Ramchandra Patil	B.Pharm (M.Pharm., Ph.D-Neuropharmacology)	Chair Person
3	Dr. Rahul Prakash Bhavasar	MBBS (MD-Pharmacology)	Member Secretary
4	Dr. Vaishali Bapurao Nagose	MBBS (MD- Pathology)	Medical Scientist
5	Dr. Shubhangi Devendra Chaudhari	MBBS (DGO,DNB-Obstetrics and Gynecology)	Clinician
6	Dr. Prashant Sudhakar Warake	B.E (MBA,Ph.D)	Social Scientist
7	Ms. Swara Jayesh Waghodkar	HSC, SSC (B.Com)	Lay Person
8	Dr. Nilesh Prakash Bendale	MBBS (MD-Community Medicine)	Clinician
9	Dr. Shivaji Pandurangrao Sadulwad	MBBS (MS-General Surgery)	Clinician
10	Dr. Girish Ashok Kulkarni	BE (ME, Ph.D-Electrical Engineering)	Member

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Pledge to the Profession

As a Molecular Diagnostic Laboratory Professional, we pledge to uphold our duty to Patients, the Profession and Society in ethical way by:

- Placing patients' welfare above our own needs, desires and pressures.
- Ensuring that each patient receives care that is safe, effective, efficient, timely, equitable and patient-centred.
- Maintaining the dignity and respect for profession.
- Ensuring laboratory's competence, impartiality, judgement or operational integrity and maintaining confidentiality of information.
- Promoting the advancement of profession.
- Redressing potential conflicts in competing interests if exist, shall be openly and appropriately declared.
- Ensuring collegial relationships within the clinical laboratory and with other patient care providers.
- Improving access to laboratory services.
- Promoting equitable distribution of healthcare resources.
- Complying with laws and regulations and protecting patients from others' incompetent or illegal practice.
- Changing conditions where necessary to advance the best interests of patients.

Date:01.11.2020

LAB DIRECTOR

Molecular Diagnostic Laboratory,
Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

QUALITY OBJECTIVES

1) To ensure 100% quality performance at each stage (Pre to post) of testing and analysis.
2) To maintain the standard turnaround time of all examinations.
3) To enhance customer satisfaction.
4) To reduce equipment downtime.
5) To ensure acceptable performance in External Quality Assessment Scheme.
6) To enhance skill, competency and knowledge of employees through regular training programmes.
7) To adhere by statutory & regulatory requirements.

Date: 01.11.2020

LABORATORY DIRECTOR

Molecular Diagnostic Laboratory,
Department of Microbiology
Dr. Ulhas Patil Medical College& Hospital, Jalgaon

QUALITY POLICY

MDL-DUPMC is committed to carry out reliable, accurate and timely testing related to COVID19, HCVsamples by:-

* Following Good Clinical Laboratory practices, complying with ISO 15189: 2012, ICMR, CDC, CLIA& NABL 112.
* Following requirement of national and international standards for testing.
* Providing best quality of services to satisfy customer's requirements.
* Creating awareness amongst the staff about established policies and procedures
* Providing training to employees to update and enhance their skills, knowledge & competence.
* Ensuring effective implementation of Laboratory Management System in day to day activities.
* Ensuring proper maintenance and calibration of equipment. Monitoring, measuring and continually improving the conditions affecting the test.

The Policy is communicated to all the employees and is reviewed once in year for its suitability and its effectiveness.

Date: 01.11.2020

LABORATORY DIRECTOR

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Sr no	Name	Designation	Academic and Professional Qualifications*	Specialization	Experience related to present work (in years)	Trainings/ Seminars attended (Externally)	Blood Group	Contact No. & Email Id
5.	G. Prashanth Kumar	Assistant Professor/Quality Manager	M.Sc Medical Microbiology	Microbiology	7 Years	1.Quality Management System and Internal audit in Medical Lab as per ISO 15189:2012 2) One day training on RT-PCR	B +ve	Mob:9848086874 ID: prashanth8687@gmail.com
6.	Dr.Hemant Bhagwan Patil	Sr.Technician/ Technical Manager	PhD (Biotechnology), M Sc (Biotechnology)	Biotechnology	11 Years	1.Quality Management System and Internal audit in Medical Lab as per ISO 15189:2012 2) One day training on RT-PCR	AB +ve	Mob-9975069575 Hpatil41@gmail.com
7.	Amol Mohan Chaudhari	Sr. Technician	B.Sc. M.L.T. DMLT	Blood Bank	12 Years	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	AB –ve	Mob:9423506264 ID: shreeprince78@gmail.com
8.	Pranjal Nilkanth Patil	Technician	B.Sc DMLT	Microbiology	2years	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	A +ve	Mob:9049111345 ID:pranjalpatil766@gmail.com

F/LOS, Iss/Rev. No: 01/00, Iss /Rev. Date: 01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Sr no	Name	Designation	Academic and Professional Qualifications*	Specialization	Experience related to present work (in years)	Trainings/ Seminars attended (Externally)	Blood Group	Contact No. & Email Id
9.	Aaftab Danish Mohd Aasif	Technician	DMLT	Pathology	1.5Year	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	B+ve	Mob:9028128483 ID:danishshaikh1865@gmail.com
10.	Pathan Nayeem Hasan khan	Technician	DMLT	Pathology	1 Year	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	O +ve	Mob: 7058574107 ID: pathannayeemkhan8013@gmail.com
11.								

Date: 01/11/20

Quality Manager

F/LOS, Iss/Rev. No: 01/00, Iss /Rev. Date: 01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

List of Staff

Sr no	Name	Designation	Academic and Professional Qualifications*	Specialization	Experience related to present work (in years)	Trainings/ Seminars attended (Externally)	Blood Group	Contact No. & Email Id
1.	Dr.Kailash Bhimrao Wagh	Professor and HOD	MD(Micro), DCP	Microbiology & Pathology	13 Years	1.Quality Management System and Internal audit in Medical Lab as per ISO 15189:2012, 2) One day training on RT-PCR	O +ve	Mob- 9975328703 , email- kwkailashwagh8@gmail.com
2.	Dr. Vipin Narendra Todase	Assistant Professor	MD (Pathology)	Pathology	2 Years	1) Awareness Training on QIA ISO 15189:2012 2) One day training on RT-PCR	AB +ve	Mob-7498433883 Vips.todase@gmail.com
3.	Dr.Shirish Renurao Gondane	Assistant Professor	MD (Pathology)	Pathology	2 Years	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	B +ve	Mob-8237539260 Shirishrg09@gmail.com
4.	Vitthal Somnath Shinde	Assistant Professor	MSc. Medical Biochemistry (Ph.D. registered)	Biochemistry	10Years	1) Awareness Training on ISO 15189:2012 2) One day training on RT-PCR	B +ve	Mob 9860652597 vitthalsshinde@rediffmail.com

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

MRM Attendance Sheet

Date and Time: -02.12.2020 at 2.00 PM
Venue: - Lab Director's Office

Sr. No	Name of Employee	Designation	Sign
1	Dr. Kailash B. wagh	lab director	
2	G. Prashanth Kumar	Quality Manager	
3	Dr. Vipin Todase	Dy. Quality Manager	
4	Dr. Shirish Gordane	Asait Professor	
5	Ms Vitthal somnath shinde	Asst. Professor	
6	Dr. Hemant Bhagwan Patil	Technical manager	
7	Amol chaudhari	Sr. Technician	
8	Poonjal Nilkanth patil	Technician	
9			
10			

Page No.
Date 24 05 21

Molecular Diagnostic Laboratory - DUPMC Jalgaon

Departmental Meeting held on 24th May 2021 at MDL. Started at 10:30 AM.

Agenda:- 1) Expected to get 2000 to 3000 Samples Per Day,
2) For above agenda preparation & Requirements
3) AOB.

Minutes:-

1. Dr. Kailash B. Wagh Sir Greeted member & welcomed for today's meeting.

2. The Lab Director Sir Informed that we are going receive 2000 to 3000 Samples Per day from Govt. PCH

3. Shift Duties & responsibilites of everyone Same as we Dissused & aggreed in previous meeting.

4. Lab Director Sir asked for requirement list to Mr. Prashanth.

5. the requirements of Kits & Consumables & other for 2000 sample/day accordingly.

6. Management decided to take another RR machine & Automatic Extraction Machion as soon as Possible. → Information given by Director Sir.

7. Night duty attender was Joined.

8. In sample received area alloted to 2 more

Page No.
Date 24/05/21

Trainee technician.

9. Dr. Shirish Sir Provided 2 MBBS Interns in e
Shift. to help in registration work.

10. 2 more Assistant technician are appoint
to help in Extraction & Sample Processing Sect

Meeting End at 12 PM.

Members Present in meeting
1. Dr. Kailash B. Wagh
2. Mr. Prashanth K. Guddeti
3. Dr. Shirish. G
4. Mr. Bitopan Das
5. Ms. Priya K
6. Ms. Aakansha
7. Dr. Vittal Shinde
8. Dr. Hemanth Patil
9. Mr. Amol Chaudhary
10. Mr. Pranjal
11. Mr Gaurav
12. Mr. Nayeem
13. Mr. Aakash
14. Mr. Nilesh
15. Mr Shoeb
16. Mr. Nanda Kishor
17. Ms. Shamim
18. Mr. Ahmed.

Page No.
Date 26 03 21

MDL-DUPMC, Jalgaon - Departmental Meeting Held on 26/03/21.

Agenda:- Discussion & conformation on duties & Sample receiving from government Hospitals.

Members Present:

1. Dr. Kailash B. Wagh
2. Dr. Shirish
3. G, Prashant
4. Bitopan Das
5. Amol Chaudhari
6. Ranjal Patil
7. Naeem Patan
8. Danish
9. Aakash
10. Nilesh
11.
12.

-> Meeting is started at 11 AM.

-> Greeting to the members by the Lab Director

-> Noted that we have received kit from Pune from government sector.

-> Expected to receive 250/day from near by PHC.

-> NEW technician (Aakash & Nilesh) should training within Few days. who are appointed by Civil Hospital, Jalgaon.

-> To each shift 2 Rn's should done (Morning & Evening)

-> Roster will be Prepared for duties.

-> Data operator need to be appointed.

-> 9-5 Morning shift & Evening shift 3-11 PM.

Page No.
Date 26/03/21

→ Morning shift — Mr. Anvi, Bansal, Akash, & Danish

→ Bansal should train Mastermix & Patan ale

→ second shift → Dr. Hemant, Patan, Nilesh.

→ Danish should cooperate & take handover duties from both shift.

→ Cleaning (work area) should done after finishing your duty.

→ Lock the entry area.

→ Consumable are noted down what we need.

→ After this meeting Lab-Director Sir is going to meet management for giving the information that we received kits from CIVIL & other necessary needs indent is going to be in front of management for further conformation

→ Meeting ended at 1 PM.

Page No.
Date 20 04 2021

MDL – DUPMC, Jalgaon

Departmental meeting Held on 20/4/21 at Molecular Diagnostic Laboratory. Started at 10:30 AM.

Agenda :- 1) Excepted to Receive 1000 Sample/day
2) Discussion & conforming responsibilities & Duties of Concern Staff.
3) AoB.

Minutes :-

1. Discussed & aggreed on this allotment of Duties.
2. Sample receiving → Mr. Bitepan Das along with one technician should receive.
3. Sample Preparation & Extraction : by Mr. Pramjal
   Mr. Nitesh
   Mr. Nayeem
   Mr. Aakash
   Mr. Shoeb.
   Mr. Gaurav
4. Discussion related to shift Duties : There will be 3 shifts. Morning Shift – 8AM to 3PM
   Afternoon shift – 3PM to 9PM
   Evening shift :- 6PM to 12 AM.
5. The technician's who are going attend the shifts as follows: Morning Shift :- Pramjal & Gaurav
   Afternoon Shift : Nayeem & Shoeb
   evening Shift : Aakash & Nilesh
   on this discussions duties aggreed by technicians
6. Master Mix & PCR Loading : In section the

Page No.
Date 20 04 21

responsible Persons are Dr. Hemanth Patil,
Mr. Amol Chaudhary
Dr. Vittal Shinde.
Ms. Priya
Mr. Bitopan

7) Master Mix duty allotment to 2 shifts Morning & E

8) In the Morning Shift: Mr. Amol &
Evening Shift: Dr. Hemant Patil

9) Incase of emergency Master Mix & PCR loadin
should be handled by Dr. Vittal Shinde
Dr. Priya
Dr. Bitopan Das.

10) Before going for master mix doing Persons shou
ask about number sample then arrang accordi

11) Summary Sheet Preparation responsibility gi
to Dr. Prashanth K. Guddeti.

12) Results Entry in ICMR Portal responsibility gi
to Ms. Bakansha Mam.

13) store updates & Issue update by Dr. Prashsir &
Prashanth

14) Dr. Hemanth given with responcibility re bot
all technical Problem take care.

15) Registration staff should be attend 2 shifts

16) AOB:- Requested to provide attender in shift

Page No.
Date 20/04/21

→ Requested for 3 more technicians for further use.

Meeting End at 1 PM.

Members Present :-

1. Dr. Kailash B. Wagh
2. Mr. Prashanth Kumar
3. Dr. Shirish G
4. Dr. Hemanth Patil
5. Mr. Bitopan Dey
6. Mr. Amol Chaudhari
7. Dr. Vittal Shinde
8. Ms. Priya K.
9. Ms. Akanksha
10. Mr. Bansal
11. Mr. Gourav
12. Mr. Nayeem
13. Mr. Shoeb
14. Mr. Nitesh
15. Mr. Aakash.

F/FMC, Iss/Rev. No: 01/00, Iss/Rev. Date: 01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Management Committee

The following committee is formed to review the Organization's Management System as per the requirement of ISO 15189:2012 to ensure its continuing suitability, effectiveness & adequacy. The meeting of the same shall be held once in quarter or earlier if required. Management Representative (Quality Manager) shall communicate about the meeting & also maintain the records of the minutes of the meeting.

Members:

1. **Lab Director**
2. **Microbiologists/Pathologist/Doctors**
3. **Quality Manager**
4. **Technical Manager**
5. **Dy. Quality Manager**
6. **Dy. Technical Manager**
7. **Lab Staff**

The agenda of the meeting shall include but not limited to the following:

a) The periodic review of requests, and suitability of procedures and sample requirements;

b) Assessment of user feedback;

c) Staff suggestions;

d) Internal audits ;

e) Risk management;

f) Use of quality indicators;

g) Reviews by external organizations;

h) Results of participation in inter-laboratory comparison programmes (PT/EQA);

i) Monitoring and resolution of complaints;

j) Performance of suppliers;

k) Identification and control of nonconformities;

l) Results of continual improvement including current status of corrective actions and preventive actions;

m) Follow-up actions from previous management reviews;

n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

o) Recommendations for improvement, including technical requirements.

Date:01.11.2020

Lab Director

F/MRM, Iss/Rev. No: 01/00, Iss/Rev. Date:01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Minutes of Management Review Meeting

Ref. no.: MRM/01

Management review meeting - **Date and Time: -** 02/12/20 **at** 2.00 pm

Venue: - Lab Director's Office

Proceedings: -

I Following members of management committee were present.

1. Lab Director
2. Microbiologists/Pathologists/Doctors
3. Quality Manager
4. Technical Manager
5. Dy. Quality Manager
6. Dy. Technical Manager
7. Lab Staff

II Following points were discussed in the meeting

a) The periodic review of requests, and suitability of procedures and sample requirements;

The review related to request, suitability of procedures and sample requirement is carried out. Standard documentation of the same is initiated as per NABL requirements. The agreements with the hospitals as well as other authorities will be made. The requirements of the sample quantity, transportation etc. specified and training related to it given to person going to transport the sample. Sample collection is not under the scope of the lab. The hospitals and other administration will take the cognizant of the same and sent the sample to the lab. The information about the test carried out and facilities provided to the customer. The lab was specially designed for the analysis of SARS CoV-19/HCV samples. Customer was informed about requisition slip required for Cov-19/HCV requirements. For any hospital as a customer review request is to be carried out by Technical manager.

b) Assessment of user feedback;

The process of availing the customer feedback has been initiated. The facility for registering feedback/suggestion/complaint is made available with the lab. No specific complaints has been received. The feedback forms from few customers are received. Customer satisfaction index to be calculated by the quality manager. As the lab is newly built, therefore there were no such complaint right now.

c) Staff suggestions;

The facility for gathering the staff suggestion has been provided. The suggestions of the staff will be reviewed and implemented on quarter basis. The review of suggestions from the staff is to be carried out and actions to be planned by Lab Director.

d) Internal audits;

F/MRM, Iss/Rev. No: 01/00, Iss/Rev. Date:01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

1. Regular training of staff related to RT-PCR testing. SARS CoV-19/HCV testing, safety related to customer communication, quality assurance
2. Proper identification of work area, registers, files.
3. Cleanliness and improvement in washrooms
4. Availability of first aid box,
5. 1% Hypochloride use during disposal & record.

m) follow-up actions from previous management reviews;

As this is first MRM as per NABL, no follow-up actions are required. Overall review of informal meeting carried out previously and the actions decided are reviewed. Effectiveness of same evident.

n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

No major Changes in the volume and type of work undertaken. Renovation of the lab is under process.

o) recommendations for improvement, including technical requirements.

PT programme participation.

Providing training on Analysis of RT PCR testing for SARS CoV-19/HCV.

Safety Audit, Employee Suggestion Box

III Points as per implementation

SN	Implementation	Action		Remarks
		Responsibility	Target	
1.	NABL Accreditation	Lab Director	30/12/20	In process
2.	PT/EQAS programme participation process	Lab Director	15/12/20	carried out
3.	Staff development through trainings, Competency evaluation	Quality Manager	carried out	carried out
4.	Medical Checkup of staff	Lab Director	Carried out	In process
5.	Customer satisfaction survey & index	Quality Manager/ Technical Manager	10/12/20	In process
6.	Housekeeping, Sanitation of lab, Safety	Technicians	30/11/20	carried out
7.	Identification of equipment	Technical Manager	10/12/20	carried
8.	Quality Policy and Quality Objective Display	Lab Director	5/12/20	carried
9.	Compliance on pending internal audit findings	Quality Manager	30/12/20	In process
10.	Separate room & dedicated BSC/Laminar flow for PTC	Lab Director	30/12/20	In process

3/12/20

Quality Manager

F/MRM, Iss/Rev. No: 01/00, Iss/Rev. Date:01.11.2020

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

The internal audit has been conducted on 01/12/20, total 16 NCRs were raised. The compliance of the same is in process. It was asked by the lab director to complied all the non conformity raised during the internal audit at the earliest upto 30/12/2020

e) Risk management;

The risk assessment and control for work & its potential failures are considered. However structured documentation of the same will be prepared. The various risk associated with SARS CoV-12/HCV are followed. The lab has constructed as per BSL-2. Therefore, all the risk involved in testing were considered and corrective measures were taken. The most important risk is disposal of sample, spillage of sample, sanitation (personnel, lab, equipments) were considered.

f) Use of quality indicators;

The quality indicators for the lab are already established. The performance of the same is established through setting the objectives and targets. Overall performance of the same was at place. PT programme participation process is in process.

g) Reviews by external organizations;

Till date no external particularly NABL has assess the lab, but ICMR has assessed reviewed and approved for the SARS-COV-19/HCV testing.

h) Results of participation in interlaboratory comparison programmes (PT/EQAS);

Lab has participated in ILC for Covid19 & HCV. For HCV, lab will get registered itself with EQAS CMC, Vellore programme in Jan21 batch.

i) Monitoring and resolution of complaints;

Till date no complaints have been registered. Facility for registering the complaints/suggestions to be provided at sample collection room.

j) Performance of suppliers;

The list of approved suppliers with list of critical consumables, reagents is not available prepared. The overall performance of supplier is not reviewed and carried out as the lab is yet to start its working, once the lab will be functional will evaluate the supplier.

k) Identification and control of nonconformities;

The record of nonconformities are maintained followed by CAPA & effectiveness of same was ensured. All the non conformity raised during the audits were considered for CAPA.

l) Results of continual improvement including current status of corrective actions and preventive actions;

Performance report related to Quality objective is yet to prepared the same was discussed in the meeting.

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Circular

The management review meeting will be held on 02/12/2020 ..... at Lab Director's Cabin at 2.00PM ..... Management Committee members are requested to attend this meeting

The agenda of the meeting shall include but not limited to the following:

a) the periodic review of requests, and suitability of procedures and sample requirements;

b) assessment of user feedback;

c) staff suggestions;

d) internal audits;

e) risk management;

f) use of quality indicators;

g) reviews by external organizations;

h) results of participation in interlaboratory comparison programmes (PT/EQAS);

i) monitoring and resolution of complaints;

j) performance of suppliers;

k) identification and control of nonconformities;

l) results of continual improvement including current status of corrective actions and preventive actions;

m) follow-up actions from previous management reviews;

n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;

o) recommendations for improvement, including technical requirements

Date: 01/12/2020

Quality Manager

National Accreditation Board for Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

MOLECULAR DIAGNOSTIC LABORATORY, DEPARTMENT OF MICROBIOLOGY, DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL (A UNIT OF GODAVARI FOUNDATION)

has been assessed and accredited in accordance with the standard

ISO 15189:2012

"Medical laboratories - Requirements for quality and competence"

for its facilities at

NH NO.6, BHUSAWAL ROAD, JALGAON, MAHARASHTRA, INDIA

in the field of

Medical Testing

Certificate Number: MC-4029

Issue Date: 21/12/2020 **Valid Until:** 20/12/2022

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Identity : GODAVARI FOUNDATION

Signed for and on behalf of NABL

N. Venkateswaran
Chief Executive Officer

National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

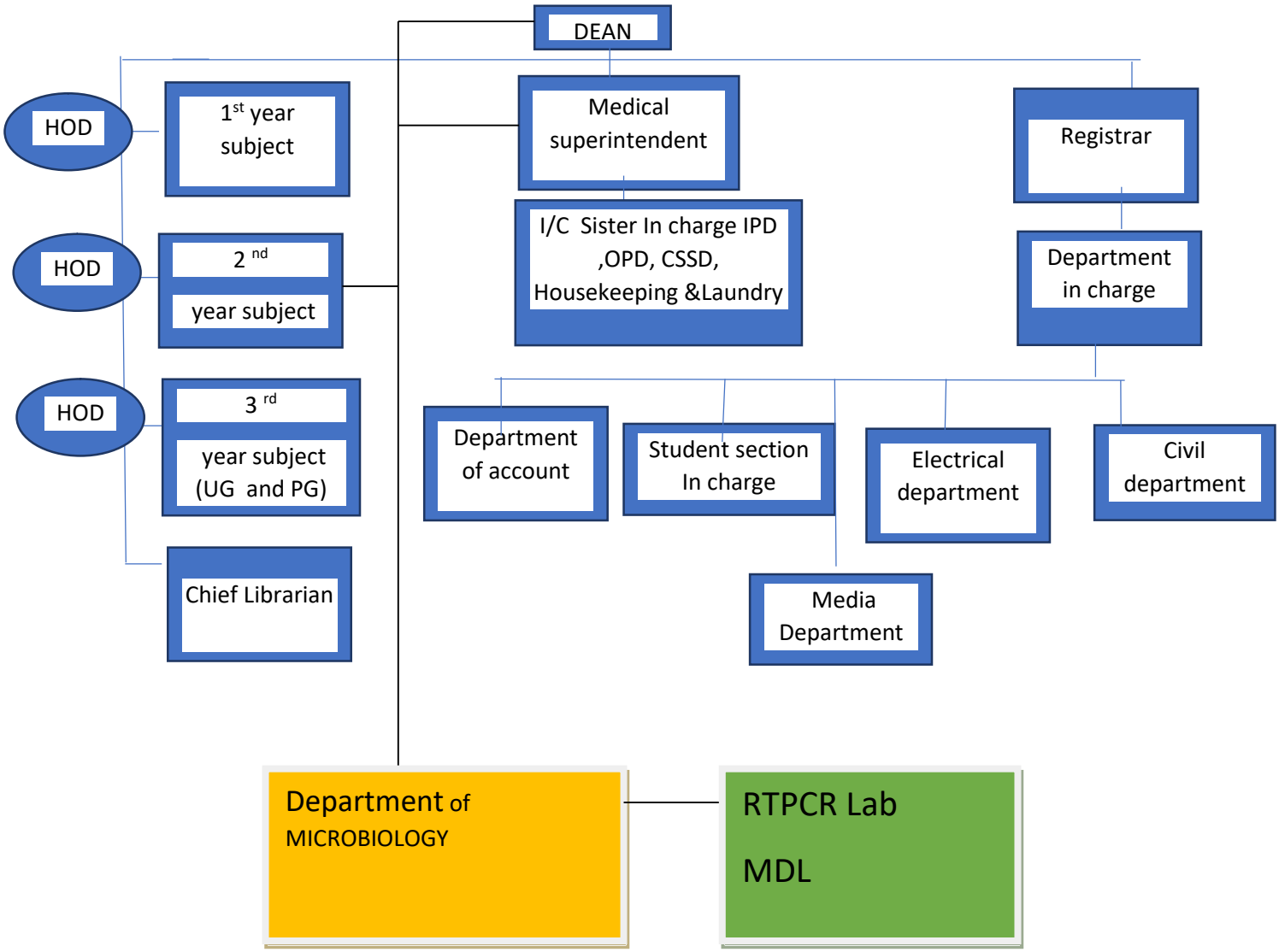
Laboratory Name :	MOLECULAR DIAGNOSTIC LABORATORY, DEPARTMENT OF MICROBIOLOGY, DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL (A UNIT OF GODAVARI FOUNDATION), NH NO.6, BHUSAWAL ROAD, JALGAON, MAHARASHTRA, INDIA
Accreditation Standard	ISO 15189:2012
Certificate Number	MC-4029
Validity	21/12/2020 to 20/12/2022

Last Amended on -

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	MOLECULAR TESTING	Blood	HCV RNA Qualitative	Real Time RT PCR (Open System)

Molecular Diagnostic Laboratory, Department of Microbiology
Dr. Ulhas Patil Medical College & Hospital, Jalgaon

Organization structure of institute



अखिल भारतीय आयुर्विज्ञान संस्थान नागपुर
प्लॉटनं. 2 , सेक्टर 20 मिहान,
नागपुर 441108
दूरभाष/Tele : +91 (712) 2980351
मेजर जनरल (डॉ) विभा दत्ता, एस.एम.
एमडी(पैथ),पीएचडी (एम्सदिल्ली), एमआईएसी
निदेशकऔरसीईओ

All India Institute of Medical Sciences
Plot No. 2, Sector 20, MIHAN
Nagpur 441108
ई.मेल/E-mail – directoraiimsnagpur@gmail.com
वेबसाइट/Website – www.aiimsnagpur.edu.in
Maj Gen (Dr) Vibha Dutta, SM
MD (Path), PhD (AIIMS Delhi), MIAC
Director & CEO

No. AIIMS/NGP/DIR COVID (test)/2021/157 Date: 27 /05/2021

To,

Dr. Narayan Arvikar,

Dean

Dr. Ulhas Patil Medical College, Jalgaon, Maharashtra

Subject: Final approval for carrying out COVID 19 Testing by RT PCR.

Dean Dr Arvikar

With reference to communication DO letter no. VIR/4/2020/ECD-I dated 9th April, 2020 from Director General – Indian Council of Medical Research (ICMR), your application has been reviewed. Department of Microbiology AIIMS, Nagpur, has gone through the required documents and quality control check. They have also reviewed the facility including infrastructure, equipments, and trained staff at Dept. of Microbiology, Dr. Ulhas Patil Medical College, Jalgaon, Maharashtra and found it appropriate for conducting COVID-19 testing by Real Time PCR.

Dept. of Microbiology, Dr. Ulhas Patil Medical College, Jalgaon, Maharashtra is hereby approved for carrying out COVID-19 testing by Real Time PCR (Private Lab NABL accredited).

All India Institute of Medical Sciences • Nagpur •

Copy to:-

1. DG-ICMR, MoHFW, Govt. of India, New Delhi.
2. Director, All India Institute of Medical Sciences, Ansari Nagar, New Delhi.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: 03/03/2017
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2016/ Minutes of Meeting

DATE: 02/12/2016

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (025[redacted]7 Fax : [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 29/02/2016

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 01/03/2016 at 3.00 pm

All members are requested to attend meeting

JALGAON

DEAN
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Copy to all members

1. Dr. B. D. Samant
2. Dr. Chandrayya Kante
3. Dr. Omprakash Bairy
4. Dr. Sachin Ingle
5. Dr. S. V. Chaudhari
6. Dr. D. R. Chaudhari

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] 2366657 Fax : [redacted] 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 1/06/2016

CIRCULAR

All members of PVC, committee are informed that meeting is arranged in Dean's office on 2/06/2016 at 3.00 pm

All members are requested to attend meeting

DEAN
DEAN
Dr.Ulhas Patil Medical College
& Hospital,Jalgaon Kh

Copy to all members

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S.V. Chaudhari
6	Mr. Bapurao M.Bite

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: 01/09/2016
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2016/ Minutes of Meeting

DATE: 02/06/2016

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S.V.Chuadhari	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. D. R. Chaudhari is appointed as Chairman and Mr. Bapurao M.Bite from Pharmacology department is added as new member in PVC committee.
2) No ADR reported from clinicians.
3) It was decided to visit clinicians personally and explain the importance of reporting.
4) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2058557 Fax : 2058548 E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 31/08/2016

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 01/09/2016 at 3.00 pm

All members are requested to attend meeting

DEAN
Dr.Ulhas Patil Medical College
& Hospital,Jalgaon Kh

Copy to all members

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: 01/12/2016
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2016/ Minutes of Meeting

DATE: 01/09/2016

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 01/12/2016

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 02/12/2016 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Minutes of meeting:-

1) One ADR reported to either IVP dye, tab. Cefixime or to tab. Paracetamol
2) Case was discussed, causality assessed and treatment discussed
3) It was decided to report this ADR to KEM hospital, Mumbai for further processing.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office

Date: 01/06/2016

Time: 03.00 pm

Dr Balwant D. Samant

Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2016/ Minutes of Meeting

DATE: 01/03/2016

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. B. D. Samant	Chairman	DUPMC, Jalgaon	Absent
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. CHAUDHARI	Member	DUPMC, Jalgaon	
6	Dr. D. R. Chaudhari	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery

ii) To assess their causality with the drug

iii) To see whether such reactions are reported from other places

iv) Reporting this ADR to ADR monitoring centre (AMC).

v) Discussion about increasing awareness of ADR monitoring and reporting

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: 15/11/2017
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 02/06/2017

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 03/06/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2017/ **Minutes of Meeting**

DATE: 13/09/2017

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 12/09/2017

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 13/09/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S.
Pin - 425 309

Phone: (0257) 3058569
Fax: (0257) 3058548

PVC/ 2016/ **Minutes of Meeting**

DATE: 03/06/2017

Location: Dean's Office
Recorded By: Dr. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari	Member	DUPMC, Jalgaon	
6	Mr Bapurao M Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm

Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery

ii) To assess their causality with the drug

iii) To see whether such reactions are reported from other places

iv) Reporting this ADR to ADR monitoring centre (AMC).

v) Discussion about increasing awareness of ADR monitoring and reporting

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2016/ Minutes of Meeting

DATE: 03/03/2017

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: 03/06/2017
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) [redacted] Fax : [redacted] E-Mail Id : dupmcj@yahoo.in
2366657 2366648

Date:- 01/03/2017

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 03/03/2017 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Minutes of meeting:-

1) No ADR reported from clinicians from hospital and periphery
2) It was decided to visit clinicians and explain the importance of Pharmacovigilance.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm

Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office

Date: 13/09/2017

Time: 03.00 pm

Dr D R Chaudhari

Chairman

5) Also in meeting it was decided to change one member i.e. Mr. Bapurao M.Bite to Dr. Rahul Prakash Bhavasar as Mr. Bapurao M.Bite resigned.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: Feb. 2019
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2018/ Minutes of Meeting

DATE: 21/11/2018

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	
7.	Dr. Rahul Prakash Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting
vi) To discuss about change of one member i.e. Mr. Bapurao M.Bite to Dr. Rahul Prakash Bhavasar.

Minutes of meeting:-

1) One ADR reported from dermatology department
2) Reactions to Acyclofenac, Paracetamol, Amoxiciline and Clavulanic acid.
3) These reactions were discussed and causality was assessed.
4) It was decided to send the ADR forms to zonal centre.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 20/11/2018

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 21/11/2018 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite
7	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2018/ Minutes of Meeting

DATE: 20/06/2018

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 19/06/2018

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 20/06/2018 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Aryikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2017/ Minutes of Meeting

DATE: 04/01/2018

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. D. R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. S. V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Mr. Bapurao M.Bite	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) Two ADRs reported from dermatology department
2) Reactions to Metronidazole and IV contrast (Omnipaque)
3) These reactions were discussed and causality was assessed
4) It was decided to send the ADR forms to zonal centre.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

6 NEXT MEETING

Location: Dean's Office
Date: April 2018
Time: 03.00 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 03/01/2018

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 04/01/2018 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL • JALGAON

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Mr. Bapurao M.Bite

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2019/ Minutes of Meeting

DATE: 18/10/2019
Location:
Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 17/10/2019

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 18/10/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2019/ Minutes of Meeting

DATE: 18/07/2019
Location:
Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's

Dr. Ulhas Patil Medical College & Hospital

Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik

N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 16/07/2019

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 18/07/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2019/ **Minutes of Meeting**

DATE: 18/03/2019
Location:
Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:- 17/03/2019

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 18/03/2019 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2020/ **Minutes of Meeting**

DATE: 14/07/2020
Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2020/ Minutes of Meeting

DATE: 04/02/2020
Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-03/02/2020

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 04/02/2020 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

4 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309

Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2021/ Minutes of Meeting **DATE: 10/06/2021**

Location: Dean's Office

Recorded By: Dr.D.R. Chaudhari

MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

1 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

2 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

3 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. Prajakta from PG from skin department has reported 5 ADRs
   a. Fixed drug eruption by ofloxacin and metronidazole on 5th April 2021
   b. Fixed drug eruption on 10th April 2021 by ofloxacin and ornidazole.
   c. Erythematous maculopapular lesion by perfenidone on 10th May 2021
   d. Toxic epidermal necrosis by carbamazepine on 18th May 2021
   e. Maculopapular rash by paclitaxel on 7th June 2021
2) These reactions were discussed and causality was assessed.
3) It was decided to send the ADR forms to zonal centre.

Meeting ended with thanks to Chairman and All Members.

Version-1.3

(1)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info avaiable.

Worldwide Unique No. :

Report Type ☑ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials	2. Age at time of Event or Date of Birth	3. M ☑ F ☐ Other ☐	4. Weight
VVP.	78		90 Kgs

12. Relevant tests/ laboratory data with dates

~~Non~~ None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy) 2/4/21

6. Date of recovery (dd/mm/yyyy) 9/4/21.

7. Describe reaction or problem

Fixed Drug Eruption.

multiple erythamatous to hyperpigmented patches on B/L lower limb, stomach.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

DM : 10 yrs.

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☑ Other (specify)

15. Outcomes

- ☐ Recovered
- ☑ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Ofloxacin	–	–	–	400	oral	OD	1/4/21	2/4/21	Post covid complication	Probable
ii	Metronidazole				100 ml	inj	BD	1/4/21	2/4/21		Probable
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i	✓								–	
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	–						
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele. DVPMC, Jalgaon.

Pin: 425309. E-mail pankaj.talele@gmail.com

Tel. No. (with STD code) 9970237310

Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 5/4/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturers or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3

(2)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type ☐ Initial ☐ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info avaiable.

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials: TPL.
2. Age at time of Event or Date of Birth: 50 yr.
3. M ☑ F ☐ Other ☐
4. Weight: 68 Kgs

12. Relevant tests/ laboratory data with dates: None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 4/4/21
6. Date of recovery (dd/mm/yyyy): 8/4/21.
7. Describe reaction or problem: Fixed Drug Eruption. Single hypopigmented patch. C vesicle around the periphery.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): Alcoholic : 20 yrs

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☑ Other (specify)

15. Outcomes
- ☑ Recovered
- ☐ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Ofloxacin.				400 mg	oral	BD	4/4/21	4/4/21	Pain in abdomen	Probable
ii	ornidazole.				200 mg	oral	BD.	4/4/21	4/4/21		Probable
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	—						
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: Dr Pankaj Talele. DUPMC, Jalgaon
Pin: 425309 E-mail: pankaj
Tel. No. (with STD code): 9970 237310.
Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 16/4/21

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3 (3)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :
Reg. No. /IPD No. /OPD No./CR no. : not 2468
Worldwide Unique No. :

Report Type: ☑ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: TPK.
2. Age at time of Event or Date of Birth: 37.
3. M ☑ F ☐ Other ☐
4. Weight: 65. Kgs

12. Relevant tests/ laboratory data with dates: Not done.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 4-5-21
6. Date of recovery (dd/mm/yyyy): 10/5/21
7. Describe reaction or problem: Erythamatous maculopapular lesion

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): no medical history.

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☑ Other (specify)

15. Outcomes
☑ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Pertenidone				200mg	oral	BD.	3/5/21	5/5/21	Covid-19 infection.	Probable
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓								✓	
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele. Dr. Vithal Patil medical college.
Pin: 425309 E-mail: pankajtalele@gmail.com
Tel. No. (with STD code): 9970237310
Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 10/5/21

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3

(4)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type ☐ Initial ☐ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info available

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials: DK.
2. Age at time of Event or Date of Birth: 20.
3. M ☐ F ☐ Other ☐
4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates: None

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 15/5/21.
6. Date of recovery (dd/mm/yyyy): 29/5/21
7. Describe reaction or problem:

Toxic Epidermal Necrosis (TEN)

- Flaccid bulla. with denodation of skin

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☑ Other (specify)

15. Outcomes
- ☐ Recovered
- ☑ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Carbamazepine.				200 mg	Oral	OD	13/5/21	15/5/21	Epilepsy	Possible
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele
DUPMC Jalgaon.
Pin: 425309 E-mail
Tel. No. (with STD code) 9970233310
Occupation: Dermatology(s) Signature: Talele.

17. Date of this report (dd/mm/yyyy): 18/5/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3

(5)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info available

Worldwide Unique No. :

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: PPK.
2. Age at time of Event or Date of Birth: 55 yrs
3. M ☑ F ☐ Other ☐
4. Weight: 62 Kgs

12. Relevant tests/ laboratory data with dates: None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 1/6/21.
6. Date of recovery (dd/mm/yyyy): 7/6/21.
7. Describe reaction or problem: Maculopapular Rash

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): DM : 18 yrs

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☑ Other (specify)

15. Outcomes
- ☑ Recovered
- ☐ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (If known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Paclitaxel	-	-	-	-	IV	OD.	1/6/21	2/6/21	Prostate carcinoma	Possible.
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	-						
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Patel
DUPMC, Jalgaon.
Pin: 425309 E-mail:
Tel. No. (with STD code) 9970234310
Occupation: Dermatologist Signature:

17. Date of this report (dd/mm/yyyy): 7/6/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-8/06/2021

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 10/06/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2021/ **Minutes of Meeting**

DATE: 30/01/2021
Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. Prajakta from PG from skin department has reported 2 ADRs
   a. Erythema multiforme developed from SODIUM VALPROATE on 7th January 2021
   b. Fixed drug eruption by meftal spas (dicyclomine + mefenamic acid) on 20th January 2021.
2) These reactions were discussed and causality was assessed.
3) It was decided to send the ADR forms to zonal centre.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-28/01/2021

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 30/01/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

(4)

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info available.

Worldwide Unique No. : INDPC-300517455

Report Type ☐ Initial ☑ Follow up

A. PATIENT INFORMATION

1. Patient Initials	2. Age at time of Event or Date of Birth	3. M ☐ F ☑ Other ☐	4. Weight
SVF	38 yr.		56 Kgs

12. Relevant tests/ laboratory data with dates: None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 7/1/2021.

6. Date of recovery (dd/mm/yyyy): 18/1/2021.

7. Describe reaction or problem: Erythema Multiforme

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): · Alcohol use : 5 yrs.

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Na Valproate.	No information available				oral	OD	4/1/21.	7/1/21.	Epilepsy.	Probable.
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None.						
ii							
iii							

Additional Information: None.

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele

Pin: 425309 E-mail: pankaj.talele@gmail.com

Tel. No. (with STD code): 9090237310

Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 10/1/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3

(5)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type ☐ Initial ☐ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info avaiable

Worldwide Unique No. : IN-PC - 30051 7381

A. PATIENT INFORMATION

1. Patient Initials	2. Age at time of Event or Date of Birth	3. M ☐ F ☑ Other ☐	4. Weight
ATS.	26 yrs.		53 Kgs

12. Relevant tests/ laboratory data with dates: None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 20/1/21

6. Date of recovery (dd/mm/yyyy): 30/1/21.

7. Describe reaction or problem:

Fixed Drug Eruption.
4 erythematous - hyperpigmented Patches; 1 over the neck & 3 over the UL.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): None.

14. Seriousness of the reaction: No ☑ If Yes ☐ (please tick anyone)

- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☐ Other (specify)

15. Outcomes

- ☑ Recovered
- ☐ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Mettalspas					oral	OD	19/1/21	20/1/21	for menstrual cramps	Probable
ii	Dicyclomine + Hydrochloride	No information available.									
iii											
iv	Mefenamic acid										

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i	✓						✓			
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None.						
ii							
iii							

Additional Information: None.

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele
DDPMC Jalgaon, Skin department.
Pin: 425309 E-mail: pankaj.talele@gmail.com.
Tel. No. (with STD code) 9970237310.
Occupation: Dermatologist Signature: Dr Talele.

17. Date of this report (dd/mm/yyyy): 22/1/21

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-23/02/2021

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 25/02/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)

DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON

PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2021/ **Minutes of Meeting**

DATE: 25/02/2021
Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. Prajakta from PG from skin department has reported 2 ADRs
   a. Fixed drug eruption by etoricoxib on 10th February 2021
   b. Acral erythema & erythrodysthesia developed from Docetaxel on 16th February 2021.
2) These reactions were discussed and causality was assessed.
3) It was decided to send the ADR forms to zonal centre.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-24/03/2021

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 25/03/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr. Chandrayya Kante
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr.Rahul Bhavasar

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2021/ Minutes of Meeting

DATE: 25/03/2020
Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
3	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
4	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
5	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	
6	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. Prajakta from PG from skin department has reported 2 ADRs
   a. Multiple oral ulcers by amoxicillin on 6th March 2021
   b. Maculopapular rash on 8th March 2021.
2) These reactions were discussed and causality was assessed.
3) It was decided to send the ADR forms to zonal centre.

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

(2)

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info available.

Worldwide Unique No. : IN-IPC-300517373

Report Type: ☑ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: VTT

2. Age at time of Event or Date of Birth: 68 yrs

3. M ☑ F ☐ Other ☐

4. Weight: 74 Kgs

12. Relevant tests/ laboratory data with dates: None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 16/2/21.

6. Date of recovery (dd/mm/yyyy): 22/2/21.

7. Describe reaction or problem: Docetaxel induced Acral erythema & erythrodysthesia.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.): None

14. Seriousness of the reaction: No ☑ if Yes ☐ (please tick anyone)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☐ Other (specify)

15. Outcomes
- ☐ Recovered
- ☑ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Docetaxel	No information available				oral	OD	14/2/21	16/2/21	Ca Prostate	Possible
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None	-	-	-	-	-	-
ii							
iii							

Additional Information: None

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele
DUPMC, Talgaon. Skin Department
Pin: 425309 E-mail:
Tel. No. (with STD code): 9970 237 310
Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 16/2/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

(6)

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type ☐ Initial ☐ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : No info available

Worldwide Unique No. : IN IPC - 300517464

A. PATIENT INFORMATION

1. Patient Initials	2. Age at time of Event or Date of Birth	3. M ☐ F ☐ Other ☐
DVF	29 yrs.	4. Weight 61 Kgs

12. Relevant tests/ laboratory data with dates

None.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy) 10/2/21.

6. Date of recovery (dd/mm/yyyy) 16/2/21

7. Describe reaction or problem

fixed Drug eruption

single erythematous to hyperpigmented patch on ® forearm

single small ulcer on genital.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

None.

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged ☐ Other (specify)
☐ Disability

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Etoricoxib	No information available				oral	BD	8/2/21.	10/2/21	for fracture Pain.	Probable.
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓	-			-	-				
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None.						
ii							
iii							

Additional Information:

None

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talele

Pin: 425304 E-mail pankaj.talele@gmail.com

Tel. No. (with STD code) 99.1523 7310.

Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 8/2/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Version-1.3 (3)

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Reg. No. /IPD No. /OPD No./CR no. : NO info available

Worldwide Unique No. : IN-IPC-30051-7475

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: ASB.
2. Age at time of Event or Date of Birth: 70 yrs
3. M ☑ F ☐ Other ☐
4. Weight: 60. Kgs

12. Relevant tests/ laboratory data with dates: Drug Allergy Testing done - 14/3/21.

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 6/3/21
6. Date of recovery (dd/mm/yyyy): 16/3/21.
7. Describe reaction or problem: multiple Oral ulcer
Multiple oral ulcers.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)
No information available.

14. Seriousness of the reaction: No ☑ if Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

15. Outcomes
☐ Recovered ☑ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Amoxycillin	No information				oral	BD	5/3/21	6/3/21	Bacterial infection	Probable Certain.
ii	ot Sulfa Drug.	available.				oral					
iii											
iv											

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓								✓	
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None.						
ii							
iii							

Additional Information:
None

D. REPORTER DETAILS

16. Name and Professional Address: Dr Pankaj Talele
DDPMC Jalgaon. Skin department.
Pin: 425309 E-Mail pankaj.talele@gmail.com
Tel. No. (with STD code) 9970237310
Occupation: Dermatologist Signature: Talele

17. Date of this report (dd/mm/yyyy): 8/3/21.

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

(1)

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :
Reg. No. /IPD No. /OPD No./CR no. :
Worldwide Unique No. : IN-IPC-300517480

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: VAF
2. Age at time of Event or Date of Birth: 56 yrs.
3. M ☐ F ☑ Other ☐
4. Weight: 45 Kgs

12. Relevant tests/ laboratory data with dates: None

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy): 8/3/21
6. Date of recovery (dd/mm/yyyy): 15/3/21
7. Describe reaction or problem:

Maculopapular rash.
multiple skin coloured to erythematous macules & papules & few confluent plaques all over body ie on trunk, UL, LL except face.

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)
DM ∴ 2 yrs.

14. Seriousness of the reaction: No ☑ if Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

15. Outcomes
☐ Recovered ☑ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i	Isoniazide	No information available.				oral	OD	8/3/21	18/3/21	Tuberculosis	Probable
ii	Pyrazinamide					oral	OD	8/3/21	8/3/21		Probable
iii	Rifampicin					Oral	OD	8/3/21	8/3/21		Probable
iv	ethambutol					Oral	OD	8/3/21	8/3/21		Probable.

S.No as per C	9. Action Taken (please tick): Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick): Yes	No	Effect unknown	Dose (if reintroduced)
i	✓									
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates: Date started	Therapy dates: Date stopped	Indication
i	None						
ii							
iii							

Additional Information:

None.

D. REPORTER DETAILS

16. Name and Professional Address: Dr. Pankaj Talati
Bapmc, Jalgaon, Skin department
Pin: 425309 E-mail: pankaj.talati@gmail.com
Tel. No. (with STD code): 9970237310
Occupation: Dermatologist Signature: Talati.

17. Date of this report (dd/mm/yyyy): 8/3/21

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://ipc.nic.in/showfile.asp?lid=650&EncHid=)

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/20213
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date:-03/09/2021

Circular

It is to inform that department of pharmacology is going to celebrate the **Pharmacovigilance Awareness Week** in our college from **18th to 22nd September 2021** as per the guidelines from **Indian Pharmacopoeia Commission.**

In that we are going to take some activities like poster presentation, essay writing, animation, or video competition.

So those who want to participate please kindly give their names to organizer or coordinators. The schedule and guidelines are as per following attachments.

Dean
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon kh.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

PHARMACOVIGILANCE AWARENESS WEEK

(17 TO 23 SEPTEMBER 2021)

DR. ULHAS PATIL MEDICAL COLLEGE AND HOSPITAL, JALGAON KHURD

Organized by –

DEPARTMENT OF PHARMACOLOGY

PROFESSOR AND HEAD –
DR. DEVENDRA RAMESH CHAUDHARI

CO-ORDINATORS –
DR. RAHUL PRAKASH BHAVASAR
DR. SUYOG CHOPADE
MR. BABURAO BITE
DR. PRAJAKTA KALBANDE
DR. SHAIKH MUBINA

Invitation to -

- Medical college – Staff and Students (Final yr students, Interns, and postgraduate students)
- Physiotherapy college – Staff and Students (Final yr students)
- Nursing college – Staff and Students (Final yr students)
- BHMS college – Staff and Students (Final yr students)

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-24/11/2021

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 25/11/2021 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr.Rahul Bhavasar
3	Dr. Nilesh R. Bhirud
4	Dr. Sachin Ingle
5	Dr. S. V.Chaudhari
6	Dr. Chandrayya Kante

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE

NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2021/ Minutes of Meeting **DATE: 25/11/2021**

Location: Dean's Office

Recorded By: Dr. D.R. Chaudhari

MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Rahul P. Bhavasar	Co-ordinator	DUPMC, Jalgaon	
3	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
4	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
5	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
6	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	

1 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

2 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

3 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) DR. Prajakta from PG from skin department has reported 9 ADRs
    a. Maculopapular rash by sulfasalazine on 06.08.21.
    b. Fixed drug eruption on 12.08.21 by ofloxacin and ornidazole.
    c. Acute generalized exanthematous pustulosis by Terbinafine on 25.08.21
    d. Fixed drug eruption on 05.10.21 by fluconazole.
    e. Fixed drug eruption on 24.10.21 by fluconazole
    f. Photosensitive malar rash on 25.10.21 by ciprofloxacin.
    g. Fixed drug eruption on 05.11.21 by fluconazole
    h. Urticarial rash by ofloxacine on 17.11.21
    i. Fixed drug eruption by diclofenac on 17.11.21

2) These reactions were discussed and causality was assessed.
3) It was decided to send the ADR forms to zonal center.

Meeting ended with thanks to Chairman and All Members.

4 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmci@yahoo.in

Date:- 11/01/2022

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 12/01/2022 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr.Rahul Bhavasar
3	Dr. Chandrayya Kante
4	Dr. Nilesh R. Bhirud
5	Dr. Sachin Ingle
6	Dr. S. V.Chaudhari

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2022/ **Minutes of Meeting**

DATE: 12/01/2022

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	
3	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
4	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
5	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
6	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-18/04/2022

CIRCULAR

All members of Pharmacovigilance committee are informed that meeting is arranged in Dean's office on 19/04/2022 at 3.00 pm

All members are requested to attend meeting

Copy to all members

Dr. Arvikar N. S.
Dean
Dr. Ulhas Patil Medical
College & Hospital, Jalgaon kh

Sr No	Name
1	Dr. D. R. Chaudhari
2	Dr.Rahul Bhavasar
3	Dr. Chandrayya Kante
4	Dr. Nilesh R. Bhirud
5	Dr. Sachin Ingle
6	Dr. S. V.Chaudhari

Godavari Foundation's
(Registered under the Bombay Public Trusts Act. 1950)
DR. ULHAS PATIL MEDICAL COLLEGE, JALGAON
PHARMACOVIGILANCE COMMITTEE
NH 6 (Jalgaon-Bhusawal Highway)
Jalgaon Khurd (Dist. Jalgaon) M. S. Pin - 425 309
Phone: (0257) 2366657
Fax: (0257) 2366648

PVC/ 2022/ **Minutes of Meeting**

DATE: 19/04/2022

Location: Dean's Office
Recorded By: Dr.D.R. Chaudhari

1 MEETING ATTENDED BY

Sr No	Name	Title	Organization	Signature
1	Dr. Devendra R. Chaudhari	Chairman	DUPMC, Jalgaon	
2	Dr. Rahul P. Bhavasar	Member	DUPMC, Jalgaon	
3	Dr. Chandrayya Kante	Member	DUPMC, Jalgaon	
4	Dr. Nilesh R. Bhirud	Member	DUPMC, Jalgaon	
5	Dr. Sachin Ingle	Member	DUPMC, Jalgaon	
6	Dr. Sunil V. Chaudhari.	Member	DUPMC, Jalgaon	

2 MEETING LOCATION

Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh) at Dean's Office

3 MEETING START TIME

Meeting Schedule Start: 03.00 pm
Meeting Actual Start: 03.05 pm

4 AGENDA

i) To discuss the Adverse Drug Reactions reported by clinicians from hospital & periphery
ii) To assess their causality with the drug
iii) To see whether such reactions are reported from other places
iv) Reporting this ADR to ADR monitoring centre (AMC).
v) Discussion about increasing awareness of ADR monitoring and reporting

Minutes of meeting:-

1) No ADR reported from clinicians.
2) It was decided to visit clinicians personally and explain the importance of reporting.
3) ADRs reported from other places were discussed

Meeting ended with thanks to Chairman and All Members.

5 MEETING END

Meeting Schedule End: 04.00 pm
Meeting Actual End: 4.15 pm

Dr. D. R. Chaudhari
Chairman

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date:-21.11.2018

PHARMACOVIGILANCE COMPOSITION

Sr No	Name	Title
1	Dr. D. R. Chaudhari	Chairman
2	Dr. Chandrayya Kante	Member
3	Dr. Nilesh R. Bhirud	Member
4	Dr. Sachin Ingle	Member
5	Dr. S. V. Chaudhari.	Member
6	Mr. Bapurao M.Bite	Member
7.	Dr. Rahul Prakash Bhavasar	Member

Dean

Dr Ulhas Patil Medical College & Hospital Jalgaon kh

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON KH

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date:-26.04.2022

PHARMACOVIGILANCE COMPOSITION

Sr No	Name	Title
1	Dr. D. R. Chaudhari	Chairman
2	Dr. Chandrayya Kante	Member
3	Dr. Nilesh R. Bhirud	Member
4	Dr. Sachin Ingle	Member
5	Dr. S. V. Chaudhari.	Member
6.	Dr. Rahul Prakash Bhavasar	Member

Dean

Dr Ulhas Patil Medical College & Hospital Jalgaon kh

1.0 OBJECTIVE

SOP

To lay down a procedure for monitoring, reporting and communication of AEFI-ICSRs in Pharmacovigilance Programme of India.

2.0 SCOPE

This SOP shall be applicable to all division of PvPI.

3.0 RESPONSIBILITY

3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.

3.2 All the Officers and Division-In-Charge shall ensure that this parent SOP has been reflected in the section.

3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer In-Charge- Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 NCC-PvPI shall engage in assisting Universal Immunization Programme (UIP) in monitoring the safety of vaccines.

5.2 Immunization Technical Support Unit (ITSU) under UIP, Ministry of Health and Family Welfare, Government of India (MoHFW/ GOI) is the collaborative unit for monitoring

Adverse Event Following Immunisation (AEFI). It coordinates with CDSCO in monitoring of vaccine safety.

5.3 AMC coordinator/ Pharmacovigilance associate shall fill suspected ADR reporting form and serious AEFI case notification form for reporting of Serious AEFI case which shall be notified to the District Immunization Officer (DIO) of the district where the vaccine was administered. This duly filled form be scanned and emailed simultaneously to DIO, State Expanded Programme Immunization Officer (SEPIO), PvPI and AEFI Secretariat.

5.4 AMCs shall be responsible for monitoring and reporting all Serious AEFI-ICSRs immediately to the DIO, SEPIO, AEFI Secretariat and NCC-PvPI. Non-serious AEFI-ICSRs shall be reported on a monthly basis to the NCC-PvPI.

5.5 NCC-PvPI shall be responsible for communicating both serious and non serious AEFI-ICSRs to ITSU and AEFI division of CDSCO and a copy to UIP.

5.6 Causality assessment of AEFI-ICSRs is entirely different method as compared to drugs; the rational approach is to communicate AEFI-ICSRs further to National AEFI committee for causality assessment.

5.7 In case, follow-up is required, NCC-PvPI (AEFI division) / UIP-ITSU/ CDSCO (AEFI division) shall approach AMCs.

5.8 For effective communication, roles and responsibilities of stakeholders for vaccines safety has been designed as follows-

5.8.1 Roles and responsibilities of PvPI

5.8.1.1 Indian Pharmacopoeia Commission, under the aegis of Ministry of Health and Family Welfare (MoHFW) functions as National Coordination Centre (NCC) for PvPI to monitor, report, collates and analyse adverse events due to medicines and vaccines.

5.8.1.2 PvPI has recognised public and private hospitals as an adverse drug reaction monitoring centres (AMCs) across India.

Table 2. WHO-UMC Causality Categories

Causality term	*Assessment criteria**
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

* All points should be reasonably complied with

The use of the WHO-UMC system

To illustrate how the system works, we suggest to first make a comparison of the criteria and wording of 'Probable' and Certain'. First of all there is one more criterion in the category 'Certain', the fourth: 'Event definitive pharmacologically or phenomenologically', i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon (for instance 'grey baby syndrome' and chloramphenicol, or anaphylaxis immediately after the administration of a drug that had been given previously). This means that any other event is automatically excluded and can never qualify for 'Certain' (even in the case of a positive rechallenge observation). For 'Certain', rechallenge information with a satisfactory outcome is requested (i.e. what has happened when the drug was first stopped and later on resumed), unless the evidence in the report is already convincing without a re-exposure. For 'Probable', on the other hand, a rechallenge is not required. To qualify as 'Certain' the interval between the start of the drug and the onset of the event must be 'plausible'; this means that there is in sufficient detail a positive argument in support of the view that the drug is causally involved, pharmacologically or pathologically. For 'Probable' the time relationship should be 'reasonable'; this is a more neutral term covering everything that is not unreasonable. Also, with regard to the second criterion, 'alternative causes', the wording is different in 'Probable'. For 'Certain' the occurrence of the event cannot be explained by any disease the patient is known to

the UPPSALA MONITORING CENTRE

The use of the WHO-UMC system for standardised case causality assessment

Why causality assessment?

An inherent problem in pharmacovigilance is that most case reports concern *suspected* adverse drug reactions. Adverse reactions are rarely specific for the drug, diagnostic tests are usually absent and a rechallenge is rarely ethically justified. In practice few adverse reactions are 'certain' or 'unlikely'; most are somewhere in between these extremes, i.e. 'possible' or 'probable'. In an attempt to solve this problem many systems have been developed for a structured and harmonised assessment of causality [1]. None of these systems, however, have been shown to produce a precise and reliable quantitative estimation of relationship likelihood. Nevertheless, causality assessment has become a common routine procedure in pharmacovigilance. The advances and limitations of causality assessment are reviewed in *Table 1* [2].

Table 1. Advances and limitations of standardised case causality assessment

What causality assessment can do	What causality assessment cannot do
Decrease disagreement between assessors	Give accurate quantitative measurement of relationship likelihood
Classify relationship likelihood	Distinguish valid from invalid cases
Mark individual case reports	Prove the connection between drug and event
Improvement of scientific evaluation; educational	Quantify the contribution of a drug to the development of an adverse event
	Change uncertainty into certainty

The WHO-UMC causality assessment system

The WHO-UMC system has been developed in consultation with the National Centres participating in the Programme for International Drug Monitoring and is meant as a practical tool for the assessment of case reports. It is basically a combined assessment taking into account the clinical-pharmacological aspects of the case history and the quality of the documentation of the observation. Since pharmacovigilance is particularly concerned with the detection of unknown and unexpected adverse reactions, other criteria such as previous knowledge and statistical chance play a less prominent role in the system. It is recognised that the semantics of the definitions are critical and that individual judgements may therefore differ. There are other algorithms that are either very complex or too specific for general use. This method gives guidance to the general arguments which should be used to select one category over another.

The various causality categories are listed in *Table 2*. The original descriptions and an explanation are presented under 'Definitions' [3]. In *Table 2* the assessment criteria of the various categories are shown in a point-wise way, as has been developed for practical training during the UMC Training Courses.

1) Assisting and coordinating with the Coordinator of the AMC for PvPI activities and smooth functioning of the AMC.

2) Assist in ensuring the adherence to the defined core principles and quality policy of PvPI.

3) Ensure the timely and effective communication with NCC-PvPI in absence of the AMC Coordinator and vice versa.

4) Handling of overall activities of AMC in case of Superannuation/transfer of the Coordinator till further appointment of the Coordinator at the centre and intimation to NCC-PvPI immediately.

5) Coordination with the AMC coordinator for awareness among healthcare professionals and patient for ADR reporting and drug safety.

6) Assisting coordinator to provide the information for adequate compliance management.

7) Foster good cooperation between Pharmacovigilance Associate, competent authorities, patients, healthcare professionals and other relevant bodies (if any) in accordance with the provisions for the conduct of Pharmacovigilance processes at AMC.

Responsibilities of the Deputy Coordinator:

1) Responsible for the conductance of the Pharmacovigilance activities and progress of AMCs.
2) Verifying the availability of all the documents at AMC as per SOP.
3) Ensure the quality of Pharmacovigilance data including the correctness and completeness submitted to the NCC-PvPI.

4) Ensure the traceability and follow-up of ADR reports and providing the information when queried from NCC/Competent authorities through the coordinator of AMC.

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

Roles & Responsibilities of Coordinator and Deputy Coordinator Of

Adverse Drug Reaction Monitoring Centres (AMCs):

With the aim to fulfil the overall quality objectives of Pharmacovigilance Programme of India (PvPI), the following guideline has been designed for all structures, process as well as the conduct of all tasks and responsibilities. If performance of the ADR Monitoring Centre (AMC) is found unsatisfactory, the Competent Authority reserves the right to derecognise the AMC, and no further correspondence in this regard will be entertained.

The Coordinators and Deputy Coordinators of the Adverse Drug Reaction Monitoring Centres (AMCs) have been assigned the following Roles & Responsibilities in order to ensure the smooth functioning of the AMCs.

Role of the AMC Coordinator:

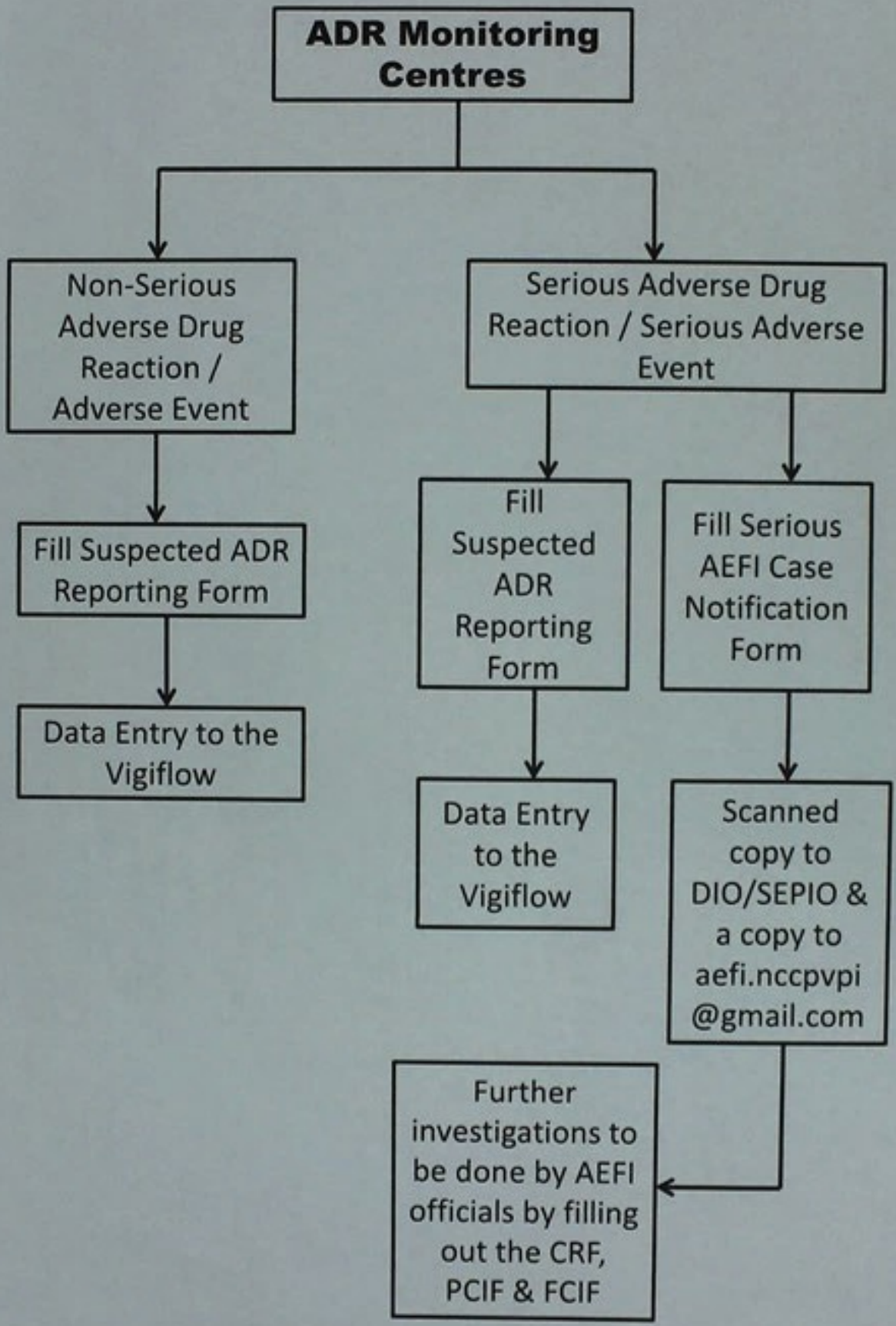
1) Establishment and capacity building of AMC and assuring the logistics & infrastructural facilities for smooth functioning of the PvPI activities.
2) Ensure adherence to the defined core principles and quality policy of the PvPI.
3) Ensure a systematic approach towards quality management system, its implementation and maintenance.
4) Meeting commitments and responding to the requests from competent authorities/NCC for correct and complete information.
5) Ensure the timely and effective communication with NCC-PvPI.
6) Communicating information to healthcare professionals and patients about Drug safety alerts and signals issued from NCC-PvPI to promote patient safety.
7) Ensure the adequate compliance management (if any) when asked from NCC-PvPI.
8) Coordination with the auditors appointed by NCC-PvPI/CDSCO in order to ensure the smooth functioning of AMC.
9) Good cooperation should be fostered between Pharmacovigilance Associate (PvA) competent authorities, patients, healthcare professionals and other relevant bodies in

accordance with the provisions for the conduct of Pharmacovigilance processes at AMC.

Responsibilities of the Coordinator:

1) Responsible for the overall performance of Pharmacovigilance activities and progress of AMC.
2) To ensure the formation of Causality Assessment Committee (CAC) and timely conductance of meetings as per SOP.
3) Ensure the availability of all the documents at AMC as per SOP.
4) Monitor and guide the Pharmacovigilance Associate (if appointed) to perform the assigned duties of PvPI.
5) Maintain the confidentiality of the Vigiflow login details and ensure timely electronic transmission of Individual Case Safety Reports (ICSRs) to NCC-PvPI through software.
6) Ensure the quality of Pharmacovigilance data submitted to the NCC-PvPI.
7) Establish mechanisms enabling the traceability and follow-up of ADR reports and ensure that it is handled and stored in a way to allow accurate reporting, interpretation and verification of that information whenever queried from NCC/Competent authorities.
8) Ensure the availability of the archiving arrangements for the electronic and/or hardcopies of the ADR reports (Source documents) at AMC and the retention of the documents as per the Pharmacovigilance norms.
9) Ensure availability of the summary / description of the training / CME / awareness / sensitization programmes on Pharmacovigilance etc. conducted at AMC including the records and certificates.
10) Ensure good Coordination/communication between the appointed PvA and various departments of the college/hospital.

Role of the Deputy Coordinator:


ADR Monitoring Centres
Non-Serious Adverse Drug Reaction / Adverse Event
Serious Adverse Drug Reaction / Serious Adverse Event
Fill Suspected ADR Reporting Form
Data Entry to the Vigiflow
Fill Suspected ADR Reporting Form
Fill Serious AEFI Case Notification Form
Data Entry to the Vigiflow
Scanned copy to DIO/SEPIO & a copy to aefi.nccpvpi@gmail.com
Further investigations to be done by AEFI officials by filling out the CRF, PCIF & FCIF

Serious AEFI Case Notification Form – ADR Monitoring Center*

ICSR No. _____ | **Reporting Format No.**

Name & address of ADR Monitoring center (AMC):	
Patient Name	
Age: _____	Sex: Male/Female
Father/Husband's Name	
Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*	
P I N -	P H O N E -
Date of Vaccination: __ __ / __ __ / __ __ __ __ Address of health facility where vaccinated (include name of village/urban area, block, DISTRICT and STATE)#:	
Name of vaccines with dose received (if known)	
Date of first symptom (D D M M Y Y Y Y)	Time of first symptom (H H M M) (AM/PM)
Hospitalization:(No/ Yes) Date- (D D M M Y Y Y Y)	Time of hospitalization (H H M M) (AM/PM)
Name and address of hospital (if hospitalized):	CR No./MRD No _____
Current status (encircle)	**Death / Still Hospitalized / Recovered & Discharged with sequelae /Recovered completely and discharged / Left Against Medical Advice (LAMA) / Not hospitalized**
If died, Date of Death (D D M M Y Y Y Y)	Time of Death (H H M M) (AM/PM)
Describe AEFI (signs and symptoms):	
Name & signature of AMC Coordinator/ Medical officer: Email: Contact No.	
*Date form sent to District Immunization Officer# (**where patient was vaccinated**)- __ __ / __ __ / __ __ __ __	
*Date form sent to State Immunization Officer# (**where patient was vaccinated**)- __ __ / __ __ / __ __ __ __	
*Date form sent to PVPI, Ghaziabad- __ __ / __ __ / __ __ __ __	
*Date form sent to Immunization Division / AEFI Secretariat (aefiindia@gmail.com)- __ __ / __ __ / __ __ __ __	
Name & signature of Pharmacovigilance Associate: E mail: Contact number:	

#The case is to be notified to the DIO of the district where the vaccine was administered.
***This form should be scanned and emailed simultaneously to DIO, SEPIO, PVPI and AEFI Secretariat.**

CONTROLLED COPY
Sign ..... Dt. 2/1/2020

INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India

Annexure-I

Log book Record for communicating of AEFI-ICSRs to CDSCO, ITSU & UIP

Format No. IPC/PvPI/NHP/001-F01

S. No.	Report ID	Report Title	Reported AMC	Reported Date	Communication Date	Signature	Remarks

	Name	Designation	Signature	Date
Prepared by	Dr. Vijit Agrawal	Sr. Pv Associate		01/01/2020.
Reviewed by	Dr. Shashi Bhushan	SSO		01/01/2020
Approved by	Dr. Jai Prakash	Sr. PSO		01/01/2020

AEFI	:	Adverse Event Following Immunisation
AMCs	:	Adverse Drug Reaction Monitoring Centres
CA	:	Causality Assessment
CDSCO (HQ)	:	Central Drugs Standard Control Organization (Head Quarter)
CRF	:	Case Reporting Format
DIO	:	District Immunization Officer
FCIF	:	Final Case Investigation Format
ICSRs	:	Individual Case Safety Reports
ITSU	:	Immunization Technical Support Unit
MoHFW/ GOI	:	Ministry of Health and Family Welfare / Government of India
NCC	:	National Coordination Centre
NRA	:	National Regulatory Authority
PCIF	:	Preliminary Case Investigation Format
PHFI	:	Public Health Foundation of India
PvPI	:	Pharmacovigilance Programme of India
QA	:	Quality Assurance
SEPIO	:	State Expanded Programme Immunization Officer
SOP	:	Standard Operating Procedure
UIP	:	Universal Immunisation Programme

9.0 ANNEXURE(s):

Annexure I : Log book record for communication of Serious AEFI-ICSRs to CDSCO, ITSU & UIP. (Format No. IPC/PvPI/NHP/001-F01)

	Name	Designation	Signature	Date
Prepared by	Dr. Vijit Agrawal	Sr. Pv Associate		01/01/2020
Reviewed by	Dr. Shashi Bhushan	SSO		01/01/2020
Approved by	Dr. Jai Prakash	Sr. PSO		01/01/2020

5.8.2.5 Responsible to coordinate with respective AMCs for further follow up/investigation in case of serious AEFI.

5.8.3 Roles and Responsibilities of CDSCO

5.8.3.1 CDSCO is the National Regulatory Authority which ensures safety, efficacy, and quality standards of pharmaceuticals, medical devices and vaccines in India.

5.8.3.2 The AEFI division of CDSCO (HQ) functions in close coordination with the PvPI, Immunization Division, and AEFI cells for continued monitoring of vaccine safety.

5.8.3.3 Regulatory actions are incited by CDSCO in case the qualities defects of implicated vaccines are indicated for the adverse event in the causality assessment report.

5.8.3.4 Drug Inspector deputed by the state drug controller and the concerned CDSCO zonal officer under whose jurisdiction the AEFI occurred, take part in joint investigation along with DIO.

5.8.3.5 CDSCO is responsible for taking appropriate regulatory decisions and actions on the basis of recommendation of PvPI and AEFI secretariat.

6.0 SAFETY AND PRECAUTIONS

6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

	Name	Designation	Signature	Date
Prepared by	Dr. Vijit Agrawal	Sr. Pv Associate		01/01/2020
Reviewed by	Dr. Shashi Bhushan	SSO		01/01/2020
Approved by	Dr. Jai Prakash	Sr. PSO		01/01/2020

5.8.1.3 The PvPI team at AMC shall be responsible for monitoring of serious and non serious AEFIs in public and private hospitals of their region and reporting to NCC. The AMC centres shall also share reported serious AEFI with the District Immunization Officer (DIO) & State EPI Officer (SEPIO) immediately in their respective centres.

5.8.1.4 A serious Individual Case Safety Reports (ICSRs) due to vaccine received at NCC-PvPI shall be immediately communicated to AEFI Secretariat & AEFI division of CDSCO for further action at their end. Whereas non serious ICSRs shall be communicated on monthly basis to AEFI Secretariat and AEFI division of CDSCO.

5.8.1.5 NCC-PvPI invites experts from AEFI Secretariat for signal review meetings.

5.8.1.6 India specific signals identified are recommended to CDSCO for appropriate regulatory actions.

5.8.2 Roles and Responsibilities of AEFI

5.8.2.1 The National AEFI Secretariat has been set up in Immunization Technical Support Unit (ITSU) through a tripartite agreement with CDSCO, PHFI and Immunization Division, MoHFW to provide technical support to the National AEFI Surveillance Programme which is a part of the Universal Immunization Program (UIP).

5.8.2.2 The National AEFI Secretariat shares the reported AEFIs with the CDSCO on a weekly basis through the soft copy as well as print copy.

5.8.2.3 AEFI Secretariat shall receive all serious and non-serious reports from NCC-PvPI and forward the information to concerned Zonal consultant for further follow up at the state and district level by the SEPIO/DIO to ensure reporting through CRF and investigation PCIF/FCIF, etc.

5.8.2.4 National AEFI Committee through its causality assessment sub-committee conducts regular causality assessment (CA) meetings for AEFI cases; summarizes the CA in an anonymized linelist for sharing with MoHFW (for public on website) and further sharing with CDSCO as part of the Indian NRA.

National Coordination Centre for Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392, Fax: 0120-2783311
www.ipc.nic.in

ADVICE ABOUT REPORTING

A. What to report?

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products etc.

  Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in)

B. Who can report?

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses etc) can report adverse drug reactions

C. Where to report?

- Duly filled inSuspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI to review the data and suggest any interventions that may be required.

E. Mandatory fields for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting

- **E-mail:pvpi@ipcindia.net or pvpi.ipcindia@gmail.com**
- ***PvPI Helpline (Toll Free):1800 180 3024****(9:00 AM to 5:30 PM, Monday-Friday)*
- ***ADR Mobile App: "ADR PvPI"***

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction by Healthcare Professionals
INDIAN PHARMACOPOEIA COMMISSION(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002

A. PATIENT INFORMATION

1. Patient Initials _____	2. Age at the time of Event or Date of Birth _____	3. M ☐ F ☐ Other ☐
		4. Weight_____Kgs

Reg. No. /IPD No. /OPD No. /CR No. :

AMC Report No. :

Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy)

6. Event/Reaction stop date (dd/mm/yyyy)

6 (A). Onset Lag Time

7. Describe Event/Reaction with treatment details, if any

12. Relevant tests/ laboratory data with dates

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)

14. Seriousness of the reaction: No ☐ If Yes ☐(please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐Hospitalization/Prolonged ☐ Other Medically important

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv*											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii*							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____

_____

Pin:_____E-mail_____

Tel. No. (with STD code)_____

Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Sig. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

*use separate page for more information

have or any other drug taken. For 'Probable', on the other hand, the event is 'unlikely' to be attributable to another cause. Also the dechallenge situations (i.e. what happened after stopping) are different. In a 'Certain' case report, the course of events constitutes a positive argument in favour of holding the suspected drug responsible, in pharmacological or pathological respects, whereas in a 'Probable' case it is sufficient if it is 'clinically reasonable' (i.e. not unreasonable).

The essential distinctions between 'Probable' and 'Possible' are that in the latter case there may be another equally likely explanation for the event and/or there is no information or uncertainty with regard to what has happened after stopping.

The criteria that may render the connection 'Unlikely' are firstly the time relationship is improbable (with the knowledge at the time), and/or another explanation is more likely. The term 'Unclassified / Conditional' is of a preliminary nature and is appropriate when, for a proper assessment, there is more data needed and such data are being sought, or are already under examination. Finally when the information in a report is incomplete or contradictory and cannot be complemented or verified, the verdict is 'Unclassifiable'.

Since by far the most frequent categories in case reports are 'Possible' and 'Probable', the usual approach to using the system is to choose one of these categories (depending on the impression of the assessor) and to test if the various criteria fit with the content of the case report. If the report seems stronger one can go one step 'higher' (e.g. from 'Possible' to 'Probable'), if the evidence seems weaker one should try a 'lower' category. To see if that category is the right one or if it does again not seem to fit, the next adjacent term is tried.

For drug-drug interactions the WHO-UMC system can be used by assessing the actor drug, which influences the kinetics or dynamics of the other drug (which has usually been taken over a longer period), in the medical context of the patient.

How does it work?

How the WHO-UMC causality assessment system can be used will be illustrated with the aid of a few real-life case reports. These will be made available on the UMC website in the near future.

1. Meyboom RHB, Royer RJ. Causality Classification in Pharmacovigilance Centres in the European Community. Pharmacoepidemiology and Drug Safety 1992; 1:87-97.

2. Meyboom RHB. Causal or Casual? The Role of Causality Assessment in Pharmacovigilance. Drug Safety 17(6): 374-389, 1997.

3. Edwards IR, Biriell C. Harmonisation in Pharmacovigilance. Drug Safety 10(2): 93-102, 1994.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL, JALGAON

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in



SKILL LAB
STANDARD OPERATING PROCEDURE
VERSION 1

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

2021 / SOP V1

MEMBERS – SKILL LAB COMMITTEE

FORMED ON -

SR. NO	NAME AND DESIGNATION and department	DESIGNATION	SIGNATURE
1	DR. RAHUL PRAKSH BHAVASAR Associate Professor (Pharmacology)	COORDINATOR	
2	DR. JAIDEO MANOHAR UGHADE Professor (Anatomy)	MEMBER	
3	DR. VITTHAL SOMNATH SHINDE Associate Professor (Biochemistry)	MEMBER	
4	DR. SHIVAJI P. SADULWAD HOD & Professor General Surgery	MEMBER	
5	DR. MAYA N. ARVIKAR HOD & Professor OBGY	MEMBER	
6	DR. CHANDRAYYA KANTE Professor Gen. Medicine	MEMBER	
7		MEMBER	

SIGNATURE OF DEAN
DUPMCHJ

Godavari Foundation's
DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,
Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

2021 / SOP V1

INDEX

SR. NO	CONTENT	PAGE NO
1	Availability of area and number of mannikins in skill lab	4
2	Rules and Standard Operating Procedures (SOPs) for Skill Laboratories	6
3	Guidelines for Maintenance and storage of manikin	7
4	Guidelines for Setting up mannikin and Steps to arrange demo	8
5	Guidelines for Steps to perform demo	8
6	List of procedures to be demonstrated	9
7	All procedures	10

1. Availability of area and number of mannikins in skill lab

Skill lab of DUPMCH, JALGAON is developed according to the guidelines of NMC and MUHS, Nashik. DUPMCH, JALGAON having a Skills Laboratory where students can practice and improve skills pre-specified in the curriculum. The purpose of the skills laboratory is to provide a safe and non-threatening environment for students to learn, practice and be observed performing skills in a simulated environment thus mitigating the risks involved in direct patient exposure without adequate preparation and supervision. The skills laboratory attempts to recreate the clinical environment and tasks which future health care workers have to perform with various levels of complexity and fidelity.

1.1 Availability of area

DUPMCH, JALGAON skills laboratory is having a total area of at least 3000 sq. feet for intake up to 200 MBBS students annually having –

i. 08 rooms are for examination of patients or standardized/ simulated patients
ii. A room for demonstration of skills to small groups
iii. Area for review or debriefing area
iv. Rooms for faculty coordinator and support staff
v. Adequate space for storage of mannequins and/or other equipment
vi. Facility for video recording and review of the interaction for teaching communication skills
vii. Stations for practicing skills individually or in groups

viii. Trainers or mannequins required to achieve skills outlined in the competency based undergraduate curriculum document

ix. A dedicated technical officer and adequate support staff.

x. The teaching areas of the skills lab having a provision for audio-visual and internet facilities and shall be enabled for e-learning soon.

1.2 Number of available mannequins are

1) First aid, Bandaging, splinting
2) Basic Life Support (BLS), CPR (Cardio Pulmonary Resuscitation) mannequin
3) Various types of injections- Subcutaneous, Intra-muscular, Intra-venous
4) Urine Catheter insertion
5) Skin & Fascia suturing
6) Breast examination model /mannequin
7) Gynaecological examination model/mannequin including IUCD (Intra Uterine Contraceptive Device) Training model
8) Obstetrics mannequins including Obstetric examination, conduct and management of vaginal delivery.
9) Neonatal & Paediatric resuscitation mannequins
10) Whole body mannequins
11) Trauma mannequin

2. Rules and Standard Operating Procedures (SOPs) for Skill Laboratories

Laboratories of training programmes provide facilities of various instrument, equipment and tools to impart the basic skills and practices.

Students in the respective Lab. are required to follow all rules, guidelines and instructions provided by the Trainer/ Lab. Staff.

General Laboratory SOP:-

1. Students expected to listen to and follow all instructions given by the instructors.
2. When working in any Lab. students should make sure that the working area should be neat and well organized. She should remember to clean the area and return the equipment(s) to the Lab. In-charge.
3. Perform/practice any skill only after the demonstration and permission given by Trainer.
4. Students have access to Lab. equipment(s)/product(s) for use as mentioned in respective course curriculum and getting hand on training.
5. A request for issuance of equipment(s)/machine(s)/product(s) will made by the student through respective Instructor.
6. Lab. Staff issues the equipment(s)/machine(s) after verifying the work ability of the equipment/machine/tools(s) or expiry date of the product.
7. After completion of the work, the equipment will be returned with the confirmation that it is in working condition.
8. Lab. Staff will verify workability of equipment and place at the designated almirah.

9. Each student should throw the waste in the appropriate dustbin during and after practice/work.
10. Maintain the required distance from other students.

Safety Rules:-

1. Always wear loose fitted clothes or apron, as instructed by the instructor.
2. No eating and drinking allowed in Lab.
3. Never play with scissors or any equipment/instrument /tools.
4. Never plug/use any electric equipment with bare feet.
5. Keep away with boiling water and fire.
6. Be vigilant, always remember the location of exits and fire extinguisher.
7. Call to Lab. staff in case of any emergency

3. Guidelines for Maintenance and storage of mannikin

a) All manikins are stored in particular box which is been provided along with it.

b) All manikins are cleaned and stored properly in box after use.

4. General guidelines for Setting up mannikin and Steps to arrange demo

a) Mannikin should be borrowed each time by the faculty for demonstration purpose.

b) Timing and date should be informed beforehand to be ready with availability to prevent intermixing of sessions.

c) At a time maximum 50 members / students can be demonstrated.

d) For better visibility mannikin should be set on the demonstration table.

e) Demonstrator should confirm that it is visible to all or he may demonstrate it in the group of 10 to 15 according to his/her feasibility or number of students available.

5. General guidelines for Steps to perform demo –

a) Demonstrator should perform the demo according to the steps of particular procedure which he is going to perform.

b) All students or understand that procedure step wise

c) To meet above need demonstrator should allow all students to perform the demonstration repeatedly and practice it to become perfect in act under supervision of demonstrator.

6. List of procedures to be demonstrated

a) **Venepuncture**

b) **Intramuscular injection**

c) **Intradermal injection**

d) **Subcutaneous injection**

e) **Intravenous injection**

f) **Setting iv infusion and calculating drip rate**

g) **Blood transfusion**

h) **Urinary catheterization**

i) **Basic life support**

j) **Oxygen therapy**

k) **Ryle's tube insertion**

l) **Lumbar puncture**

m) **Pleural and ascitic aspiration**

Venipuncture: phlebotomy

Phlebotomy

- **What does it mean?**
- Process of collecting blood
- **Greek translation**
- Phlebos:vein
- Tome: incision

Why do we need to do venipuncture?

- **For the collection of blood for**
  - For diagnosis and treatment of disease
  - Therapeutic purposes
  - Blood donation

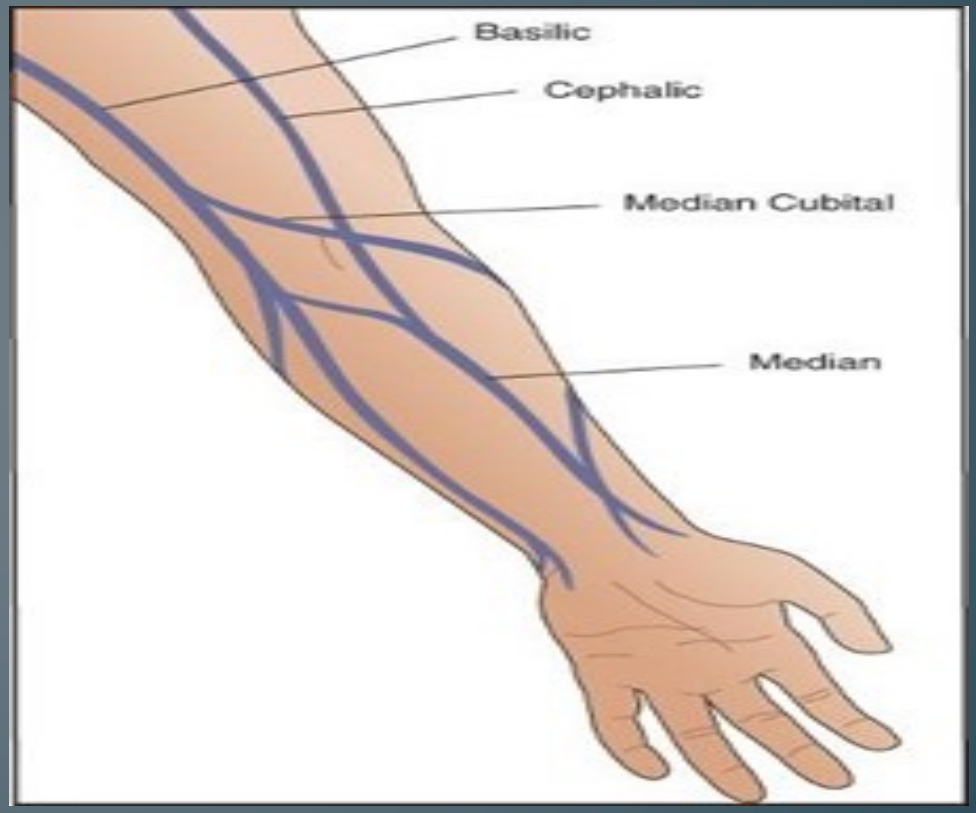
Medical asiiatant's role

- Perform accurately and efficiently
- ✓ for reliable test results
- ✓ Provide quality care
- ✓ Patient safety and confidentiality
- ✓ Phlebotomist safety

Phlebotomy sites

- Order of sites from where we can draw blood are
  - Arm:antecubital space includes
    Median cubital
    Cephalic
    Basilic
  - Veins in hand
  - Veins in feet

Preferred Sites in the arm



Venipuncture Methods

- There are three main methods of drawing blood.
  - Vacuum tube
  - Syringe
  - Butter fly

Evacuated Tube Method

This method include

- **Vacutainer tube**
- **Adapter**
- **Double-pointed Needle**

Features of this method are:

1. Closed system - needle stick risk low
2. Vacuum draws blood inside the tube
3. Safety needles meet OSHA guideline

Venipuncture Technique

- Butterfly collection system Combines benefits of syringe and vacuum methods Used for small or fragile veins that are difficult to draw.
- Winged needle inserted at about 5° angle then threaded into vein
- Syringe method:
- Used for small or fragile veins
- Control flow

Venipuncture Equipment

- Appropriate PPE (gloves, gown, goggles)
- Safety needles
- Tourniquet or blood pressure cuff(Constrict flow of blood in arm, Make veins more prominent.
- Alcohol(spirit) or Betadine
- Cotton balls or gauze-(preferred)
- Bandages or tape

Order of draw

- Why ? It is to prevent contamination.

(It may vary between laboratories)

❑Basic order

1. Sterile- sterile specimens
2. Light blue-sodium citrate
3. Red or plain tubes no additives –Serum separator tube (Red/Gray, Yellow)
4. Green –heparin
5. Lavender-EDTA
6. Gray –oxalate-fluoride

Venipuncture Technique

- **Technical skills**
- Prepare for the draw-equipment (spare tubes)
- Positioning the patient
- **Administrative skills**
- Note order-required tests and Complete the lab requisition
- **Social skills**
- Small talk (weather, pets, entertainment)
- **Good Therapeutic Communication**
- Assess patient comfort level
- Put patient at ease-show confidence
- Ask about past experiences

Preparing the patient

- identify yourself and explain the procedure Properly
- Identify your patient ask them to: State their name and date of birth
- Note fasting or non-fasting
- Ask patient about allergies
- Taking blood thinners
- Past Experiences

Always remember

- To wash your hands

To Draw the blood

- Position your patient for safety:
  - Sit
  - lie down
  - (note past history of fainting or loss of consciousness)
- Select the appropriate site and vein free of:
  - Scars
  - Hematomas
  - Pulse
- Find site that will give best blood return

Cont'd

- Palpate vein with tip of finger
- Differentiating between veins tendons and nerves
- Use the tourniquet appropriately

Proper Tourniquet Technique

- To prevent inaccurate blood test results-do not leave on longer than one minute
- Tourniquet may be applied over clothing for patient comfort
- Remove tourniquet when blood flow is achieved or prior to inserting last tube
- Always remove tourniquet prior to removing needle

Proper completion of draw

- Remove tourniquet
  Remove needle and apply safety device while Applying pressure to site (patient can assist)
- Bandage appropriately
- Tend to the safety of your patient
- Label specimen tubes in front of patient

Important Tips

- Do Not draw from a resistant patient
- Do Not draw if you are not comfortable.
- Uncooperative children must receive special care and be restrained for safety.
- Note Patient reactions, stop if patient complains of pain-assess patient
- For unsuccessful venipuncture
  - Reposition tube and needle
  - Rotate needle Advance further into vein
  - Try another tube-maybe the tube is defectiveIf you haven't succeeded in getting blood after 2 tries ask someone else to try

Challenging Patients

- **Pediatric**
  - The child, parents or guardians Approach-explain –get down to their level
  - Resistant-restraints ?
- **Geriatric**
- Physical-skin, hearing or vision impaired
- Effects of disease-stroke, arthritis, Parkinson's –tremors,
- Dementia-Alzheimer's
- Safety issues-wheelchairs, balance

Cont'd

- Dialysis or Cancer patients -fistulas and shunts (AV-arteriovenous-permanent access for dialysis)
- Long-Term Care patients, Home Care, or Hospice Patients
  - Traveling phlebotomists

Problem sites

- Burns, Scars, Tattoos
  Damaged Veins (sclerosed-thrombosed)
- Edema-swelling due to abnormal accumulation of fluid
- Hematoma-swelling or mass of blood
- Mastectomy-caution lymph node removal
- Obesity

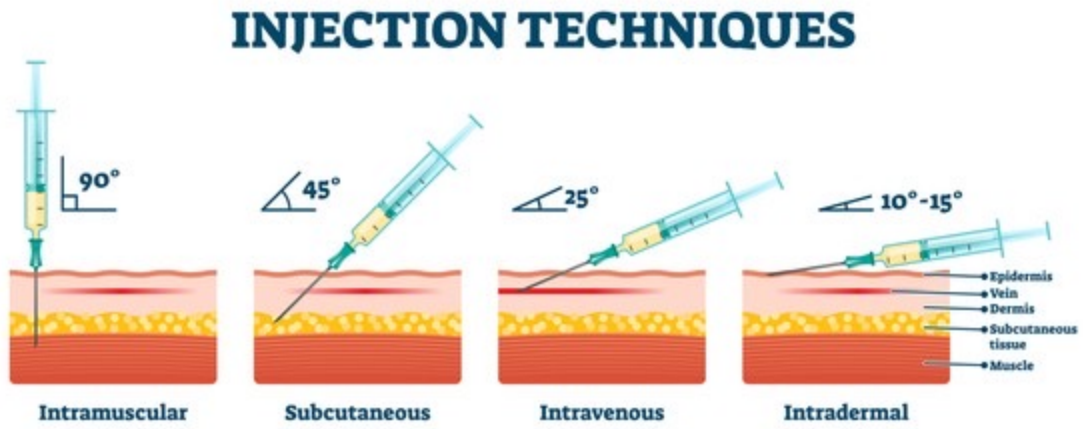
Complications or Conditions

- Allergies-adhesive, antiseptic, latex
- Excessive bleeding due to medications, hemophilia
- Fainting
- Nausea and vomiting
- Pain while drawing-what is normal –what is NOT-stopping the draw
- Seizures/Convulsions-stop draw immediately-get help

INTRAMUSCULAR INJECTION

Definition of intramuscular injection

- An intramuscular injection is when medication is injected deep into muscles. or, Intramuscular injection is the injection of a substance directly into muscle.



Purposes of intramuscular injection

- 1) It is simple and accessible.
- 2) Adsorption of drug is more rapid.
- 3) Slightly irritant drug can be given.
- 4) Moderately large volume can be given(but not more than 5 ml).
- 5) Intramuscular injection work faster and systemic effect of the drug.

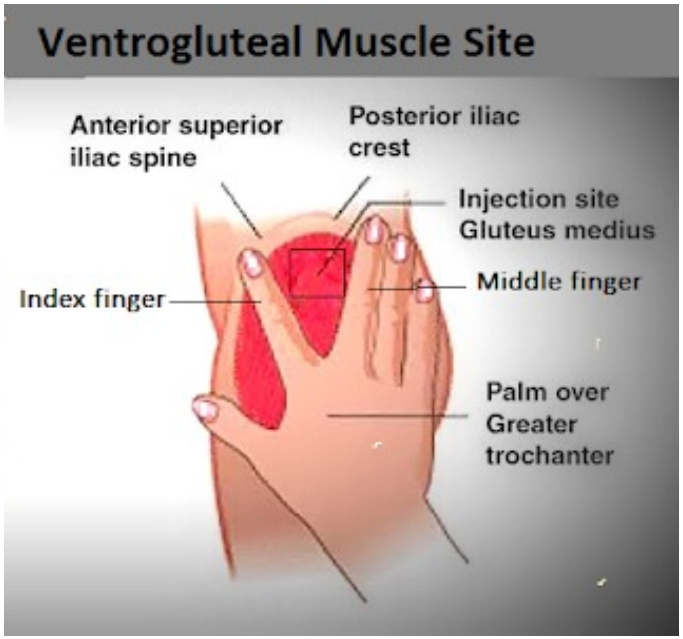
Sites of intramuscular injection

- **Deltoid**:- 2 finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla.



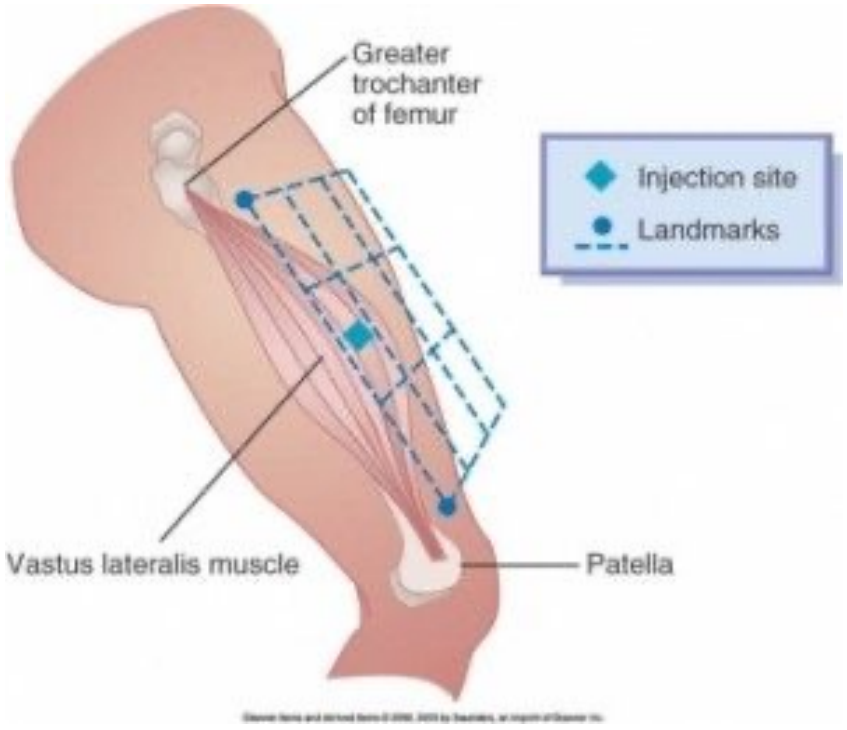
Ventrogluteal

- With thumb toward the umbilicus, place palm of hand on the greater trochanter, index finger on the anterior superior iliac & the middle finger on the iliac crest



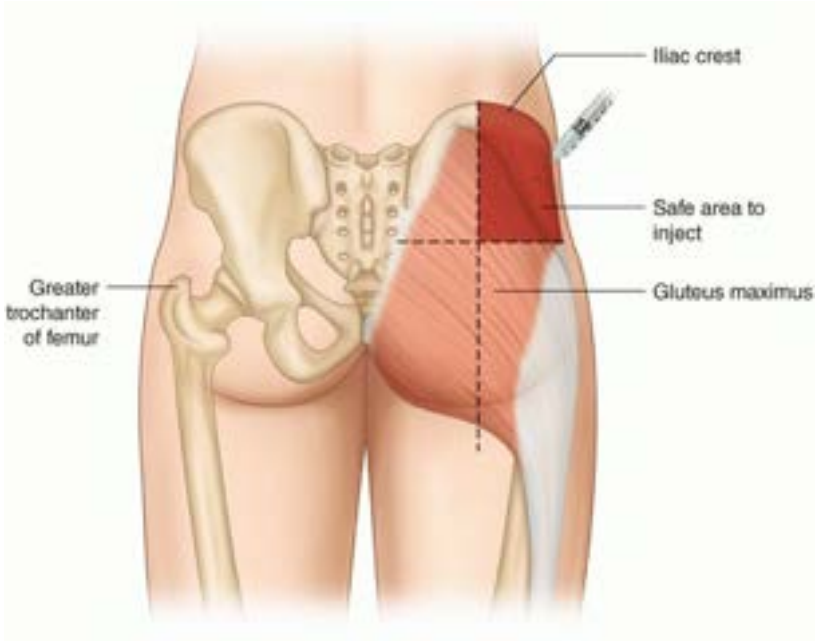
Vastus lateralis

- Place one hand below the greater trochanter & one hand above the lateral femoral condyle; mid-lateral thigh.



Dorsal gluteal

- Greatest risk of injury
- Draw an imaginary line between the greater trochanter & the posterior superior iliac spine; at the middle of the imaginary line; go up about one inch

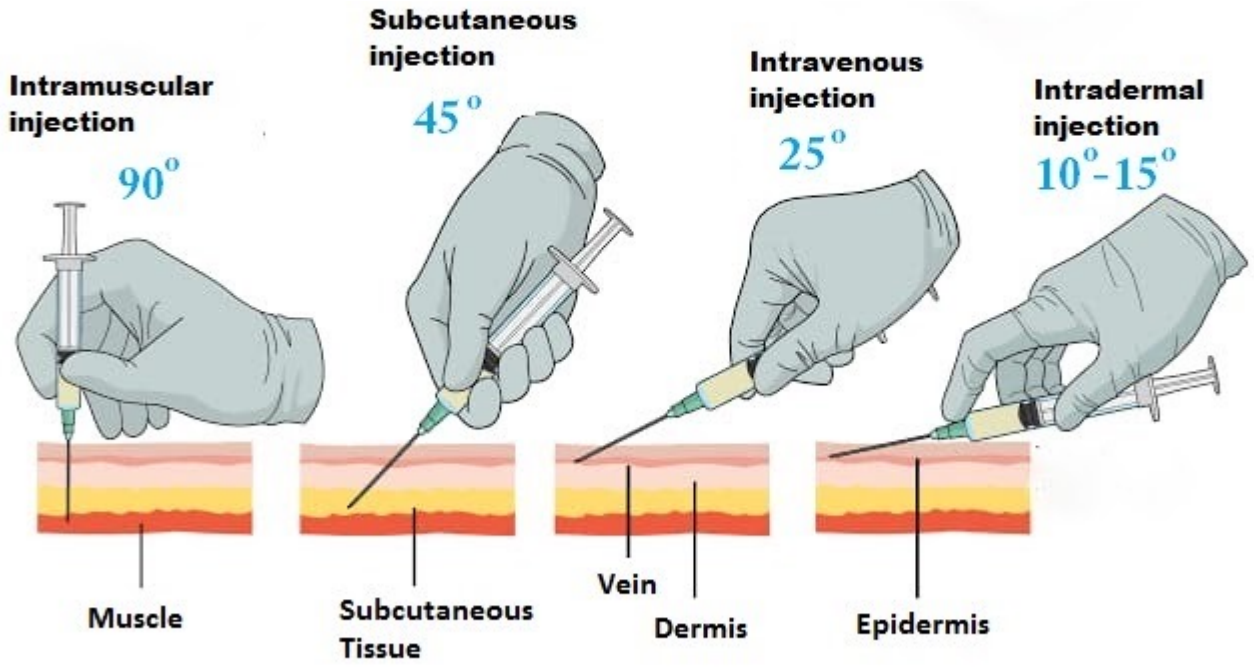


Others:-

- Quadricep site
- Rectus femoral site
- Tricep muscle

Anglesof intramuscular injection-

- Intramuscular at 90 degree angle.
- Subcutaneous at 45 degree angle.
- Intradermal at 10-15 degree angle.



INTRAMUSCULAR INJECTION

Patient age	Injection site	Needle size
New born(0-28days)	Anterolateral thigh muscle	5/8" (22-25gauze)
Infant(1-12months)	Anterolateral thigh muscle	1''(22-25guaze)
Toddler(1-2years)	Anterolateral thigh muscle Alternate site: Deltoid muscle of arm if muscle mass is adequate.	1-1¼"(22-25gauze) 5/8 -1"(22-25gauze)
Children(3-10 years)	Deltoid muscle(upper arm) Alternate site: Anterolateral thigh muscle	5/8-1"(22-25gauze) 1-1¼"(22-25gauze)
Children &adults(11years & older)	Deltoid muscle(upper arm) Alternate site: Anterolateral thigh muscle	5/8-1"(22-25gauze)s 1-1¼"(22-25guaze)

Needle Gauges for Injections Size Chart



14 GAUGE
COLOR: OLIVE
OUTER DIAMETER: .072IN (1.83MM)

15 GAUGE
COLOR: AMBER
OUTER DIAMETER: .065IN (1.65MM)

16 GAUGE
COLOR: GRAY
OUTER DIAMETER: .064IN (1.63MM)

18 GAUGE
COLOR: GREEN
OUTER DIAMETER: .050IN (1.27MM)

20 GAUGE
COLOR: PINK
OUTER DIAMETER: .036IN (.91MM)

21 GAUGE
COLOR: PURPLE
OUTER DIAMETER: .033IN (.83MM)

22 GAUGE
COLOR: BLUE
OUTER DIAMETER: .027IN (.70MM)

23 GAUGE
COLOR: ORANGE
OUTER DIAMETER: .025IN (.63MM)

25 GAUGE
COLOR: RED
OUTER DIAMETER: .020IN (.53MM)

27 GAUGE
COLOR: WHITE
OUTER DIAMETER: .016IN (.42MM)

Calculating dose

- The nurse must be prepare the dose accurately.
- The quantity for administration can be easily calculated using a standard formula.

$$\text{Drug calculation formula: } \frac{D \times Q}{H}$$

- Here, D=Desired dose
- Q=Quantity
- H=dose on hand(supplied dose)

Advantages of intramuscular injection

- i. Rapid onset of action.
- ii. Uniform absorption
- iii. Long duration of action.
- iv. Suitable for vaccine

Disadvantagesof intramuscular injection

- i. Painful.
- ii. Chance of hematoma.
- iii. Chance of neurovascular bundle injury.
- iv. Large volume can not be administered.

Precautionsof intramuscular injection

- 1) Never use the same needle & syringe to inject more than one person.
- 2) It is important to know what reactions a medicine can produce & to take the recommended precautions before injecting.
- 3) If any signs of allergic or poisonous reaction appear, never give the same or similar medicine again.
- 4) Select the proper site & needle size according to age, weight of the patient & medication viscosity.
- 5) Maintain sterile technique properly.

Procedure

1) Check patients name & medication order, including rights of administration of oral medication to the patient:-

i. Right patient.
ii. Right dose.
iii. Right drug.
iv. Right time.
v. Right route.
vi. Right assessment.
Vii. Right approach.
vii. Right education.
Viii. Right prescription.
ix. Right nurse clinician.
x. Right principle of care.
xi. Right evaluation.
xii. Right documentation.

- 2)Explain procedure to the patient.
- 3)Perform hand washing.
- 4)Withdraw medication from an ampoule or vial.
- 5)Do not add air to the syringe.
- 6)Provide for the privacy. Have the patient assume a position appropriate for the site selected.
- 7)Ensure that the area is not tender & is free of lumps or nodules.
- 8)Clean the area thoroughly with an alcohol swab, using friction. Allow alcohol to dry.
- 9)Quickly dart the needle into the tissue at a 90 degree angle.

- 10)As soon as the needle is in place, use non-dominant hand to hold the lower end of the syringes. Slide dominant to the tip of the barrel.
- 11)Aspirate by slowly(for last 5 seconds)pulling back on the plunger to determine whether the needle is in a blood vessel. If blood is aspirated, discard the needle, syringes & medication, prepare a new sterile set up & inject at another site.
- 12)If no blood is aspirated, injected the solution slowly.
- 13)Remove the needle slowly & steadily.
- 14)Assist the patient to a position of comfort.
- 15)Remove gloves & dispose of the properly. Perform hand hygiene.
- 16)Chart the administration of the medication, include the site of administration.
- 17)Evaluate the patients response to the medication within an appropriate time frame. Assess the site, if possible, within 2 to 4 hours after administration.

Complicationof intramuscular injection

- Early(days to weeks)
- Swelling
- Redness
- Pain
- Bruising/ecchymosis
- Itching
- Infections
- Allergic reaction/hypersensitivity
- Inflammation
- Solid nodules
- Lumps caused by misdistribution
- Tissue necrosis
- Embolism with blindness

Delayed(weeks to years)

- Granulomatous inflammation/foreign body reaction
- Nodules, erythematous or not.
- Migration of the implanted filler.
- Scarring.
- Asymmetry.

Nursing care plan

- Nursing diagnosis Goal Nursing intervention Evaluation
- 1) **Fear & anxiety** due to administration of intramuscular injection. To reduce fear & anxiety.
- i. Explain the procedure to the patient.
- ii. Psychological support to the patient.
- iii. Maintain patient privacy. Minimize fear & anxiety.
- 2) **Risk for developing complication.**
- To prevent complication.
- i. Proper hand washing.
- ii. Put sterile gloves.
- iii. Use sterile needle.
- iv. Pushing injection in the safe area.
- Gradually reduce complication.

- 3) Deficit knowledge about intramuscular injection. Increase knowledge by providing information about intramuscular injection.
- i. Encourage the patient.
- ii. Explain the patient about complication of intramuscular injection.
- Patient acquire knowledge about intramuscular injection.

Summary

- Intramuscular injection is the injection of a substance directly into muscle.
- In medicine, it is one of the several alternative methods for the administration of medications. Intramuscular injection is a parenteral technique that maintains several advantages over enteral techniques, making it potentially useful in the management of pain & anxiety.
- When giving intramuscular injection a nurse must be remembered that----- **"Save one life you are a hero, Save one hundred lives & You are a nurse**"
- So responsibility is the vital points for giving intramuscular injection.

INTRADERMAL INJECTION

Contents



Introduction of intradermal injection

Purposes

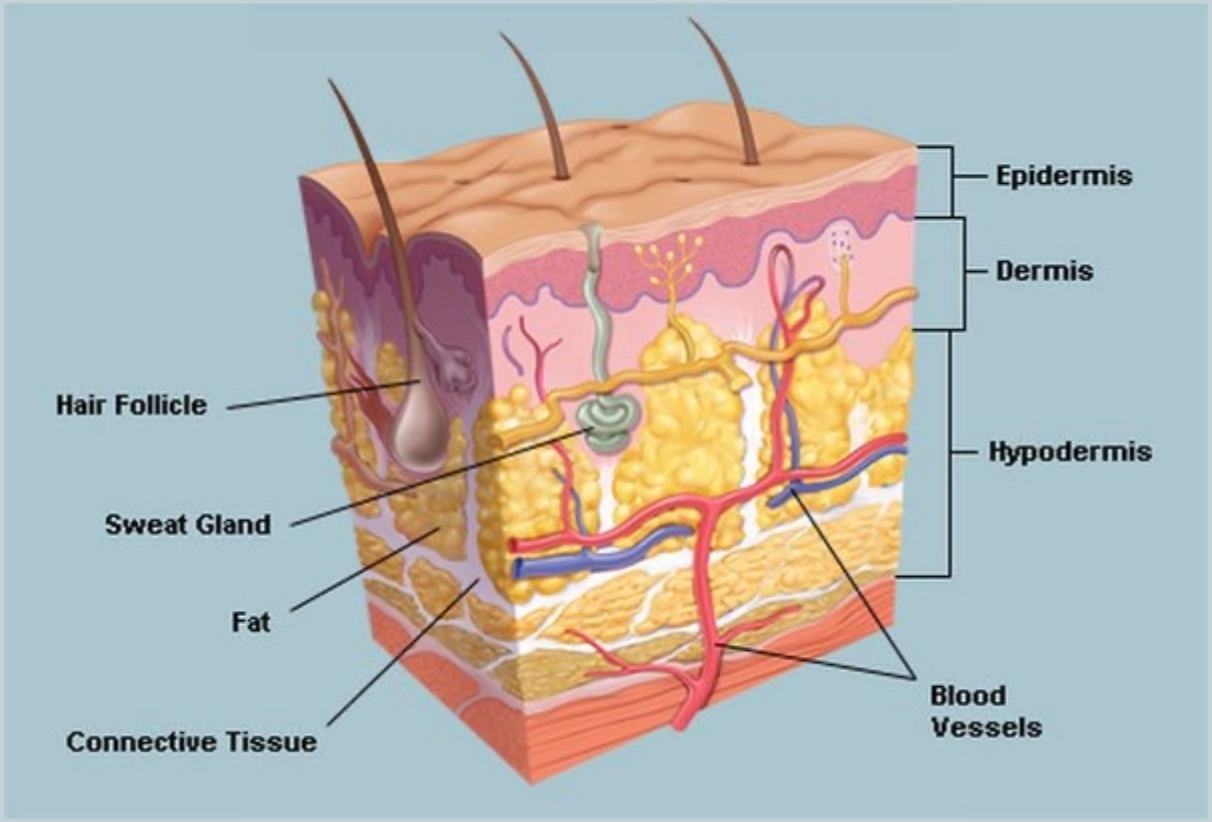
Common sites

Article required

Procedure

Complications

LAYERS OF SKIN



Intradermal injection

- The intradermal injections are administered into the dermis, just below epidermis.
- Intradermal routes has longest absorption time of all parenteral route.

Dose:

- Less than 0.5 ml
- Mantoux test 0.1 ml
- BCG 0.05 ml
- Angle of injection: 5 to 15 degrees.



Common sites

Inner surface of the fore arm.
Upper arm.
Upper back under the scapula.
Upper chest just below the clavicle.

Articles required

Medication tray containing:

Cardex

Medicine (ampule or vial)

Syringe(tuberculin syringe/ BCG syringe) and Needle(26-27 gauge)

Sprit swab.

Disposable gloves.

Kidney tray.

Ampoule cutter or opener.

TUBERCULIN SYRINGE

- Tuberculin syringe used for intradermal injection.



Procedure



- Check the physician's instructions and identify the patient.
- Explain the procedure to the patient.
- Wash hands.
- Arrange necessary articles.
- Check medication against the cardex before preparing the medication.
- Prepare the medication from ampule or vial.

Procedure

- Maintain privacy.
- Position the patient comfortably and locate the sites for intradermal injection.
- Asses the area for any scars, tenderness, tattoo , lesions, abscess etc.
- Assemble the necessary articles at patient's bed site.
- Wear disposable gloves.

- Clean the site with spirit swab in a firm circular motion (about 5 cm) and moving outward from the injection site.
- Allow skin to dry.
- In case of live vaccine (BCG Vaccine) **do not** clean the area with spirit swab, it may interfere with the viability of the vaccine. So clean the area with sterile water swab.

- Remove the cap with non-dominant hand to spread skin taut over injection site.
- Grasp the syringe in dominant hand holding in between thumb and fore finger.
- Place the needle almost against the patient skin at 5 - 15 degree angles and insert the needle into the skin with the bevel site up so that needle can be seen through the skin.
- Insert 1/8 inch of the needle.

- Slowly inject the drug, watching for a bleb / wheal or blister to develop.
- If not present withdraw the needle slightly and inject the medication.
- Withdraw needle quickly in the same angle as it was inserted.
- **Don’t massage.**
- **Don’t recap the needle**.
- Discard the needle and syringe in puncture proof container.

- Assist patient in comfortable position.
- Draw a circle using blue or black pen in injection area.
- Remove gloves and dispose them properly.
- Wash hands.
- Record and report the medication administration.

Health teaching

- Do not massage or scratch the injection site.
- Do not put anything on injection site oil, soap, powder etc.
- Keep the area clean and dry.

- Avoid putting bandage, lotions and cream to the injection site.
- If water spills in the injection site it is not harmful but do not wipe or scrub the area.
- Inform patient about the reading of mantoux and sensitivity test.

Advantage and Disadvantages

- Advantage of intradermal route of administration - Absorption is slow (this is an advantage in testing for allergies).
- Disadvantage of intradermal route-

Amount of drug administered must be small.

Complications

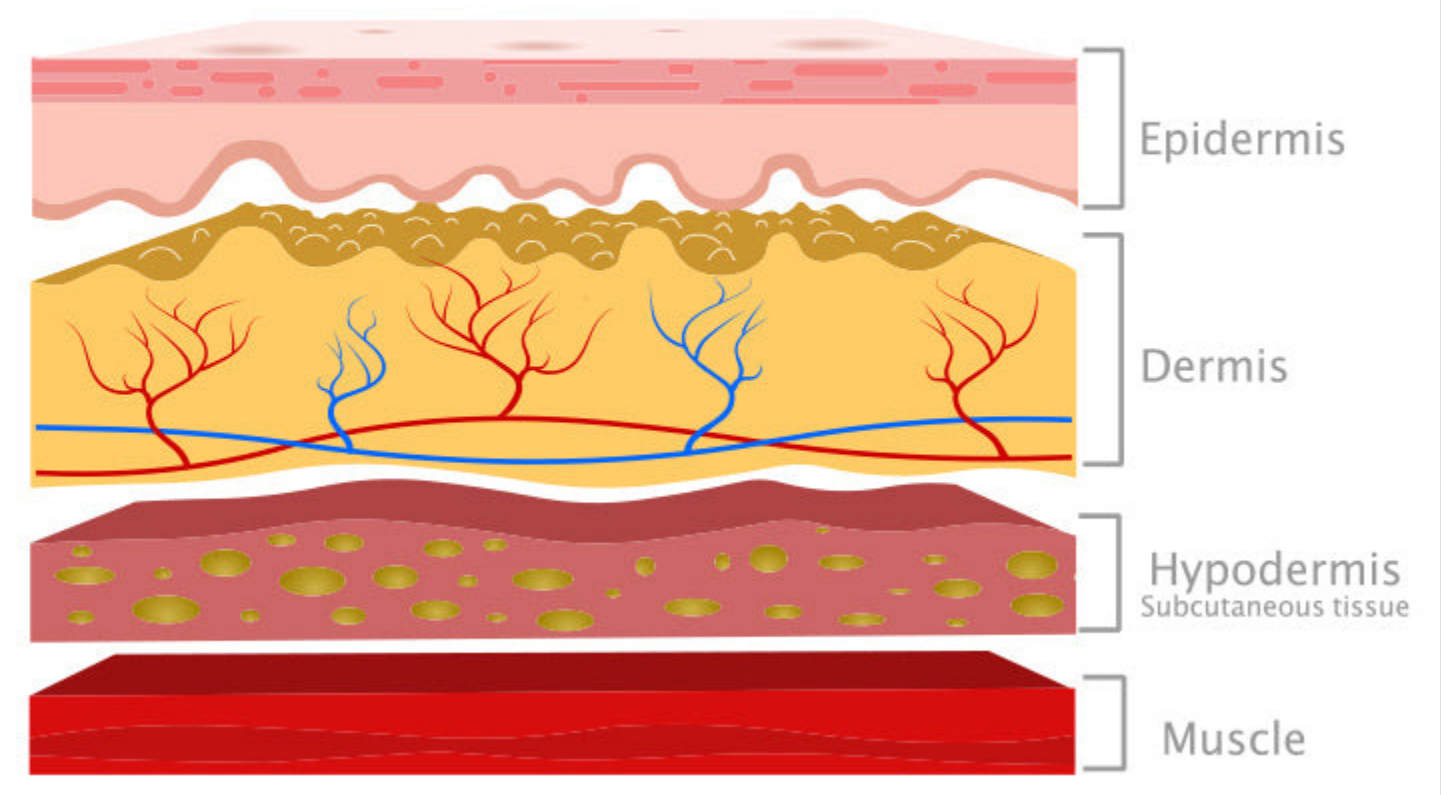
- Abscess.
- Tenderness.
- Itching.
- Irritation.
- Severe immediate allergic reactions.
- Redness.
- Keloid scar formation in case of BCG vaccination

SUBCUTANEOUS INJECTION

SUBCUTANEOUS INJECTIONS (SC)

- Drug absorption is slower than intramuscular (IM) because subcutaneous tissue is not as richly supplied with blood as the muscle.
- As the area contains pain receptors, clients may experience discomfort during injection.
- Injection site must be free of infection, skin lesions, scars, bony prominence, and large underlying muscles or nerves.

LAYERS OF SKIN



PARENTERAL ADMINISTRATION

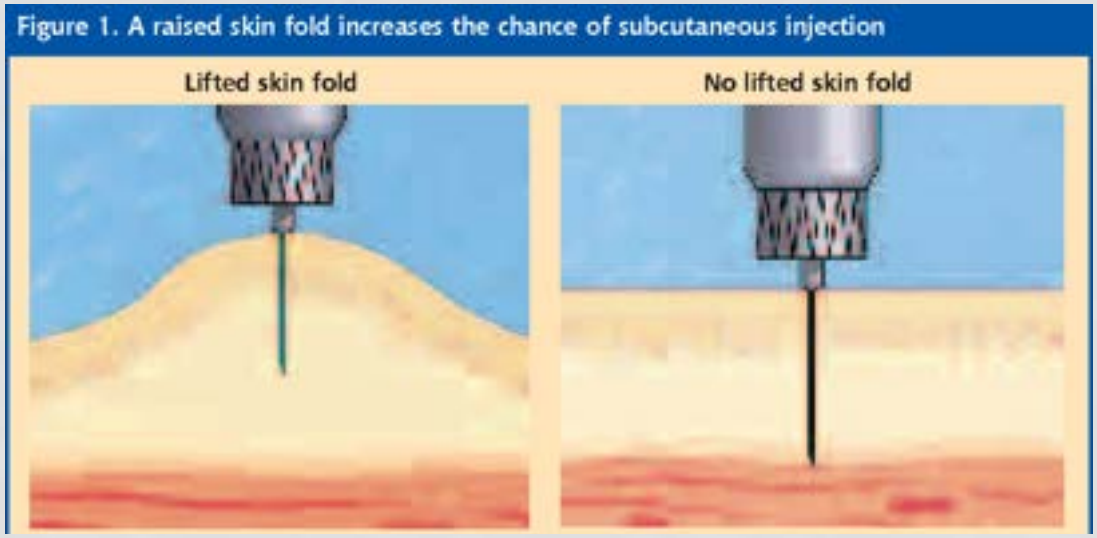
- **Subcutaneous Injections**:
- Injections made into the loose connective tissue between the dermis and the muscle layer.
- Drug absorption slower than with IM injections
- Given at a 45-degree angle if the patient is thin or at a 90-degree angle if the patient has ample subcutaneous tissue.
- Usual needle length is 1/2 to 5/8 inch and 25 gauge.
- Used to administer insulin and heparin.

SUBCUTANEOUS INJECTIONS

- Gauge-25-29G
- Length-3/8, ½ and
- 5/8 inches.
- Angle-45 degrees

SC METHOD

- Inject at 90 degree in the average client - 45 degrees if the client has small amount of subcutaneous tissue.
- (If you can pinch 2 inches, use 90 degrees, otherwise use 45 degrees)



ARTICLES REQUIRED

- A clean tray containing:
- Clean, disposable gloves.
- Medication card.
- Paper bag.
- Kidney tray.
- Puncture proof container.
- Dry and wet cotton.
- Medication vial or ampoule .
- A syringe tray containing Insulin syringe .

HEPARIN ADMINISTRATION

- Heparin - use lower abdominal folds - Arms are moved frequently and are at greater risk for tissue disruption and bruising, **do not** inject heparin (or "blood thinners" into arms)



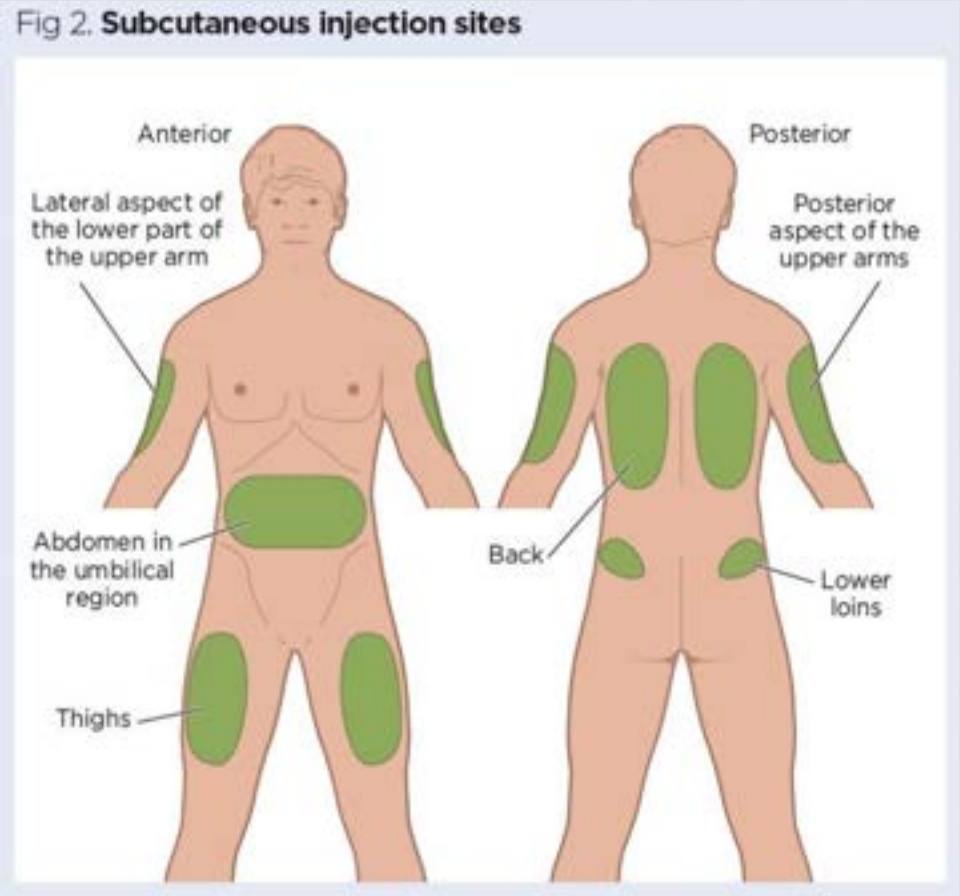
INSULIN ADMINISTRATION

- Subcutaneous administration is used for injection of insulin in Type 1 and type 2 diabetes.



INJECTION SITES

- The preferred site for giving a subcutaneous injection of insulin and heparin is the abdomen.
- Additional or alternative injection sites for insulin are the outer back area of the upper arm, where it is fleshier, and outer areas of the thigh and upper buttocks



INJECTION SITES

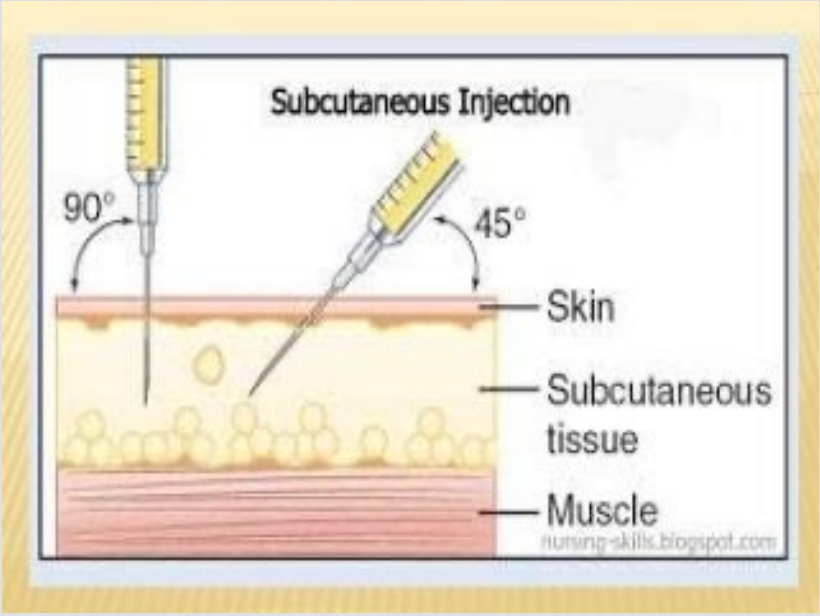
- Rotating within one injection site, preferably the abdomen, is recommended rather than rotating to a different area with each injection.
- The rate of drug absorption at various subcutaneous sites from fastest to slowest is abdomen, arms, thighs, and buttocks.

INJECTION TECHNIQUE

- To reach subcutaneous tissue in a normal-sized or obese person who has a 2-inch tissue fold when it is bunched, the nurse inserts the needle at a 90-degree angle.
- The tissue usually is bunched between the thumb and fingers before administering the injection to avoid instilling insulin within the muscle.



- **Angle for subcutaneous injection**. 45 DEGREES



ADVANTAGE AND DISADVANTAGE

- **Advantage of subcutaneous route**.
- Onset of drug action is faster than oral route.
- **Disadvantage of subcutaneous route**.
- Involve sterile technique.
- More expensive than oral.
- Only small volume of drug can be administered.
- Some drugs can irritate tissue and cause pain.

COMPLICATIONS

1. Severe pain.
2. Infection.
3. Allergic reaction.
4. Swelling.
5. Warmth or drainage.
6. Lipohyperdystrophy.

CONTRAINDICATIONS

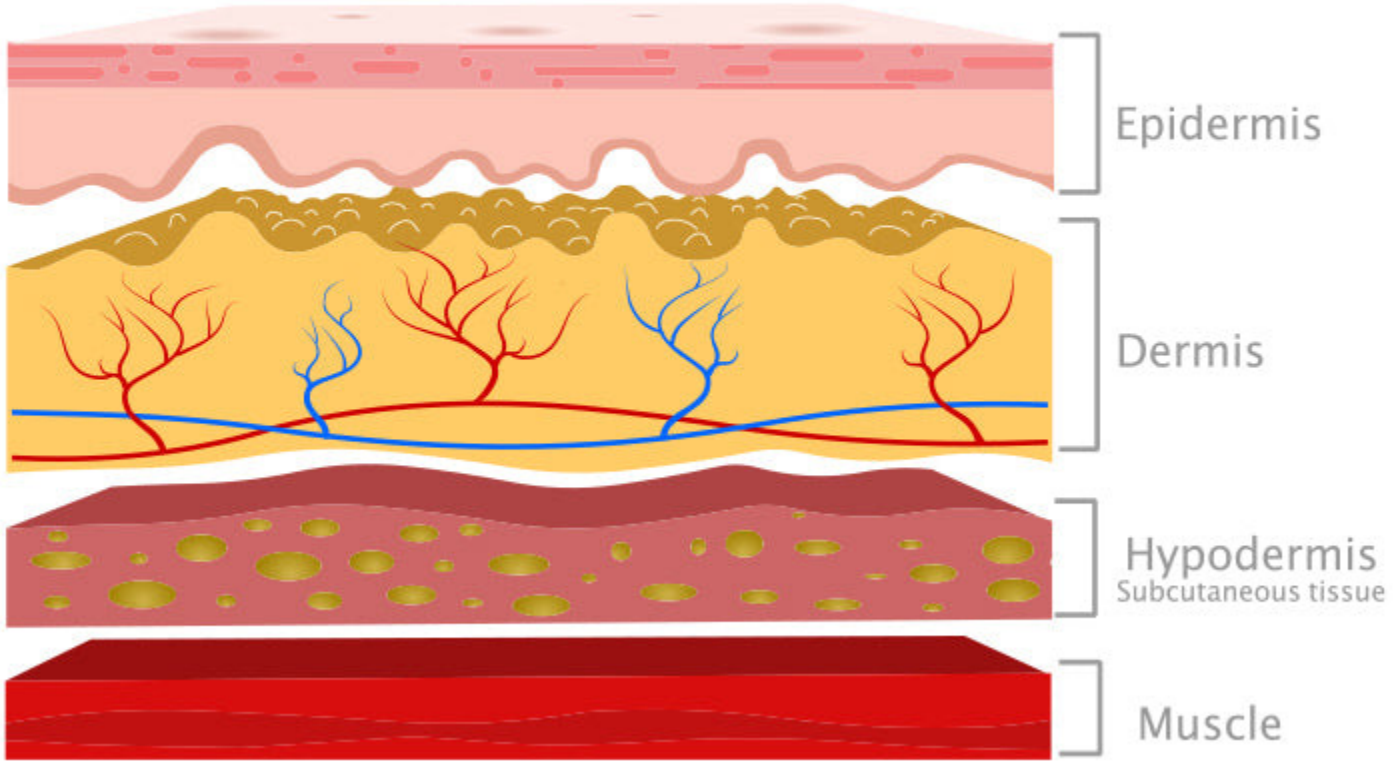
1. EMERGENCY CASES
2. MALNOURISHED
3. BURNS
4. OPEN WOUNDS
5. LARGE VOLUME OF DRUGS

INTRAVENOUS INJECTION

INTRODUCTION

- Intravenous therapy (IV) is a therapy that delivers liquid substances directly into a vein
- (intra- + ven- + -ous).
- The intravenous route of administration can be used for injections (with a syringe at higher pressures) or infusions (typically using only the pressure supplied by gravity).
- Intravenous infusions are commonly referred to as drips.
- The intravenous route is the fastest way to deliver medications and fluid replacement throughout the body.

LAYERS OF SKIN



DEFINATION

- Intravenous injection is the introduction of the small quantity of the drug into the vein by venous puncture.
- Introduction of the medicine directly into the blood stream is called intravenous injection.

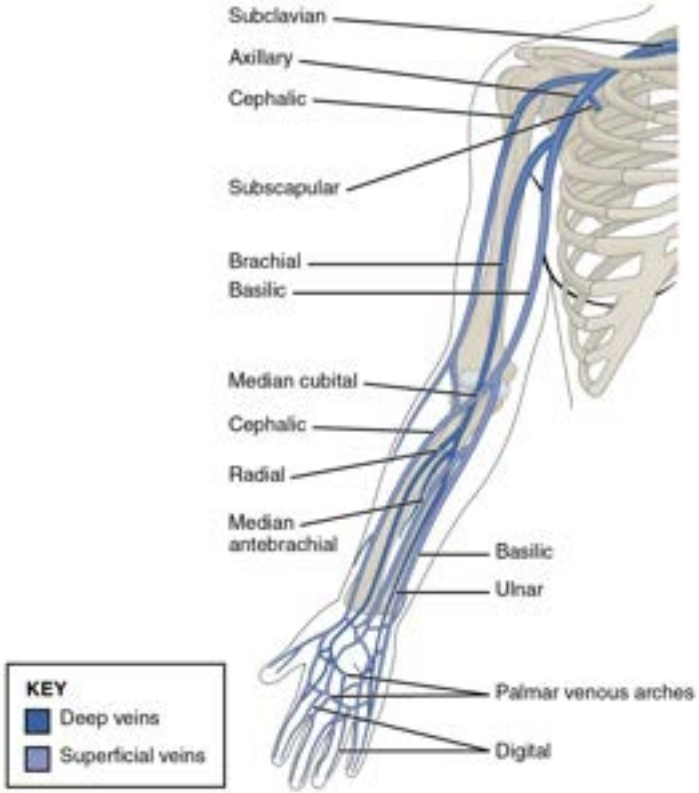
PURPOSE

- To have fast action of the drug as in emergency.
- To give medications that are irritating or ineffective when given by other routes.
- To have the actions of medicines on the blood stream or the blood vessels.

COMMON SITES OF IV INJECTION

- Ventral aspect of elbow or forearm median cubical, basilica or cephalic veins.
- Dorsal aspect of hand – brachial, cephalic or metacarpal veins.
- In the infants the scalp vein is used.

VEINS IN ARM AND FOREARM



GENERAL INSTRUCTIONS

-Expel the air from the syringe before giving the injection by upholding it in upright position and gently pressing the piston until a drop of solution comes to the tip of the needle.

-Always dissolve the drug in correct amount of fluid to minimize the risk of adverse effect of the medicine.

-Observe the patient closely for the signs of adverse reaction of the medicine and have emergency drugs and the antidote in hand while injecting the medicine.

-Do not give the medicine if the injection site shows any edema or iv solution is not following properly to avoid accidental administration of medicine into the surrounding tissues.

-When giving iron preparation always confirms that the patient is not sensitive to it by giving a test dose.

TYPE OF IV ADMINISTRATION

- Adding the medicine in iv solution bottle (intravenous infusion)
- Existing iv line for continuous infusion.
- Bolus-direct iv push for immediate or fast action..



SELECTION OF SYRINGE AND NEEDLE

- The size of syringe used for iv infusion depends upon the amount of fluids to be injected.



One cc = one ml'

- Size of the needle used are 18 to 21 gauge or 1 to 2 inches.



PRELIMINARY ASSESSMENT CHECK

- The diagnosis and age of the patient. • The purpose of injection.
- The doctors order for the type, dosage, time and route of administration.
- The patient's name and bed number. • The nurses record to find out the time at which the last dose was given.
- The symptoms of over dose or allergic reaction.
- The form of the medicine available and correct method of administration.

EQUIPMENT A TRAY CONTAINING:

- Syringe and needles of various sizes according to the need in a covered tray (sterile).
- Transfer forceps in a jar containing antiseptic solution.
- Sterile cotton swabs and gauze pieces in sterile containers.
- Methylated spirit in a container.
- Bowl with water

- Tourniquet
- Water for injection.
- Drug order sheet.
- File to cut open the ampoules.
- Small covered tray (sterile).

PREPARATION OF THE PATIENT AND ENVIRONMENT

- Identify the patient correctly.
- Explain the procedure to the patient Provide privacy.
- Place the patient in comfortable and relaxed position suitable of iv injection.
- Select a site suitable for the route of administration, quantity of medication to be given, and characteristics of medication.

PROCEDURE

- Read the doctors order and select the medication.
- Wash hands.
- Select appropriate syringe and needle and check whether they are in good working order.
- Recheck the order, medicine card with the label of the medicine, expiry date, etc .
- Mix well and take out the required amount of solution in the syringe.
- Apply a tourniquet on the upper arm.

INSERTION OF IV LINE



- Ask the patient to clench and unclench the hand.
- Pull the skin taut and place the needle in line with vein at a 10 to 30 degree angle.
- Insert the needle a bit below the point where the needle will pierce the vein.
- When the back flow of blood occurs into the syringe release the tourniquet and inject the medicine very slowly.
- Pressure with swab at the puncture site after the needle is withdrawn.

INTRAVENOUS INJECTION



AFTER CARE

- Provide the patient comfortable position.
- Observe the area for bleeding if bleeding occurs apply pressure but do not massage.
- Wash hands.
- Replace all the articles and dispose off the disposable articles.
- Ask the patient to take rest at least 15 to 30 minutes so that you can observe him for any reaction.
- Observe the patient for any allergic reaction.
- Do proper recording and reporting maintain medication chart.

ADVANTAGES OF IV INJECTION

- The therapeutic effect of the drug is seen as soon as it is administered to the patient.
- IV medication also increases the chances of removal of toxins from the body cells, accelerating the healing process.
- It also prevents the growth and spread of cancerous cells.
- Chemotherapy is given through IV route so that the drug can move about the body and destroy the harmful cancerous cell.

DISADVANTAGES OF IV INJECTION

- Very slim chances of drug recall, when the drug given to patient shows adverse effect.
- As the drug moves towards the target area quicker than the other methods the concentration of the red blood cells present in the area can get dilated leading to anemia.
- IV medications sometimes causes precipitate formation that causes embolism myocardial damage.

COMPLICATIONS WITH INTRAVENOUS INJECTIONS

- Infiltration
- Hematoma
- Air embolism
- Phlebitis and thrombophlebitis
- Extravascular injection
- Intra-arterial injection
- Allergic reaction
- Sepsis
- Speed shock

Local complication Infiltration

Infiltration occurs when I.V. fluid or medications leak into the surrounding tissue.

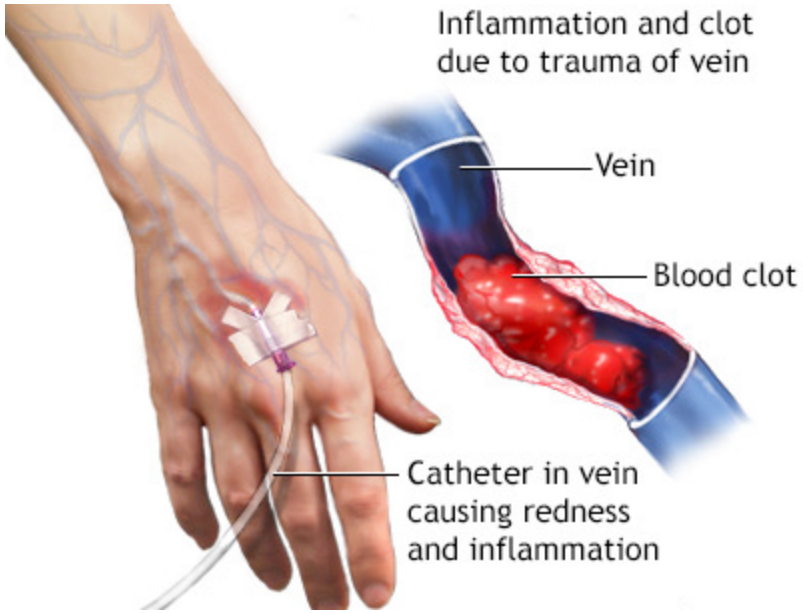
Infiltration can be caused by improper placement or dislodgment of the catheter.

LOCAL COMPLICATION Extravasation :

- Extravasation injury is defined as the damage caused by the efflux of solutions from a vessel into surrounding tissue spaces during intravenous infusion.
- The damage can extend to involve nerves, tendons, and joints and can continue for months after the initial insult.

LOCAL COMPLICATION: Thrombosis:

- Occurs when blood flow through a vein is obstructed by a local thrombus.



LOCAL COMPLICATION

- Cellulitis



LOCAL COMPLICATION

- Phlebitis

Why is phlebitis a problem?

- Phlebitis is the most common complication of having an IV line
- Unforeseen additional costs to the health system
- Painful for the patient
- Common complication of peripheral Amiodarone administration



Retrieved from Google images

NURSING RESPONSIBILITY

- To verify meds and dosage against the patient's chart and ascertain if the prescribed injection will be harmful or the prescription is misstated, and to make certain the med prescribed is viable for injection site.
- To make sure the injection site is sterile.
- To ascertain if the injection site is viable.
- To make sure the volume of the injection is compatible with the site of injection.

- To maintain sterile field and bandage properly post injection
- To monitor patient's reaction post injection to RO anaphylactic or synergistic drug reaction.
- To do proper reporting and recording.
- Medications administered by direct IV route are given very slowly over atleast 1 minute.
- Administering a medication intravenously eliminates the process of drug absorption and breakdown by directly depositing it into the blood. This results in the immediate elevation of serum levels and high concentration in vital organs, such as the heart, brain,and kidneys.
- Both therapeutic and adverse effects can occur quickly with direct intravenous administration.

THANK YOU.

SETTING UP IV INFUSION AND CALCULATING DRIP RATE

DEPARTMENT OF MEDICINE

DUPMC

IV
SET



I V SET

- The I. V. Set has three parts:
- the **Proximal limb, Murphy's chamber and the distal limb**.
- The proximal limb has asharp pointed tip which is used to puncture the outlet of the I. V. Fluid bottle or bag.
- The **Murphy's chamber** is a glass chamber that is used to regulate the flow of fluid by adjusting the number of drops falling per minute.
- The **distal limb** is consists of a long tubing with a nozzle at the end which is attached to the venous access (scalp vein, angiocath or three-way). It also has a regulator which is used to adjust the rate of flow through the Murphy's chamber.
- There may be a rubber tip just at proximal to the nozzle so that any drug can be injected bolus through it if necessary.
- They are disposable, sterile (gamma irradiation) and ready to use

TYPES OF MURPHY CHAMBER

- The main difference is in the Murphy's chamber.

- 1. **Macrodrip Set -**The Murphy's chamber is normal. 16 drops constitute 1ml. Uses 1. Fluid administration such as colloids (albumin, hemaxcele, Dextran) or crystalloids (normal saline, ringer lactate, DNS) 2, I.V. drug administration (antibiotics, iron, etc.)

- 2. **Microdrip Set -**The Murphy's chamber has a thin needle coming into it from the top. 16 micro drops constitute 1ml. Uses : Accurate small quantities of drugs have to be given I.V. (nitroglycerine, sodium nitroprusside, dopamine, dobutamine, adrenaline, noradrenaline, insulin, heparin, etc.)

- 3. **Blood Transfusion Set-** The Murphy's chamber has a filter in it to filter out any clots.

PRECAUTIONS WITH MURPHY CHAMBER

- Before connecting the I.V. Set to the venous access, the regulator should be fully opened and the fluid should be allowed to fill the Murphy's chamber up to a certain level and fill the tubing. This drives all the air in the tubing out and prevents air embolism. The fluid level in the Murphy's Chamber will prevent the air from the proximal part to enter the venous access. Thus a fluid level should always be maintained.

HOW TO START IV LINE

•GATHER YOUR MATERIAL

•Sterile disposable gloves

•Appropriate size "over-the-needle" IV catheter (typically 14 - 25 gauge)

•Bag of IV fluid

•Non-latex tourniquet

•Sterile bandage or dressing

•Gauze

•Alcohol wipes

•Medical tape

•Sharps container

•Sterile pad or paper (set small tools out on this to keep them close at hand)



INTRODUCE YOURSELF TO PATIENT



Prepare the IV tubing.



Choose a suitable-gauge catheter for the situation



Put on sterile gloves.



Look for prominent veins.



Apply a tourniquet.



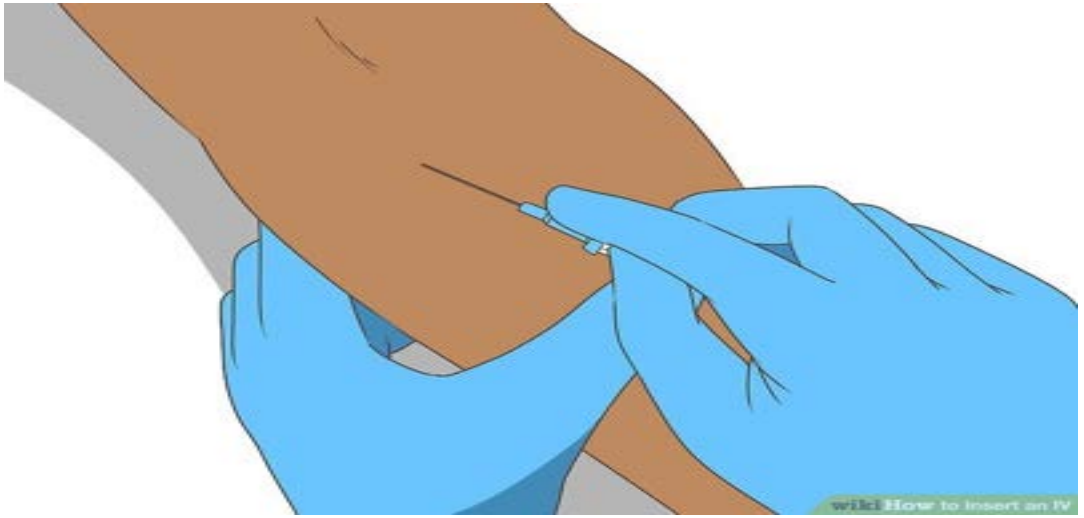
Disinfect the IV site.



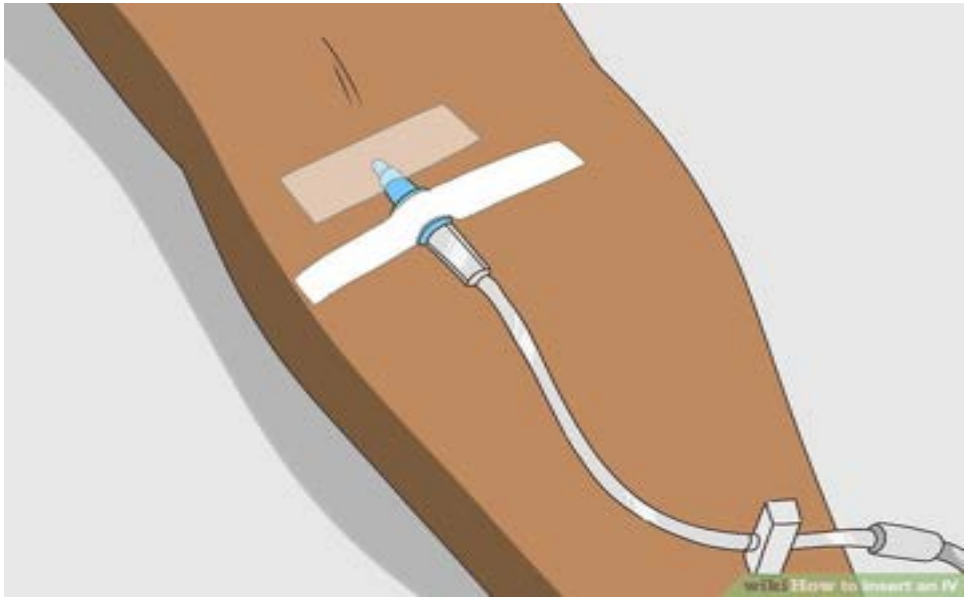
Prepare the catheter for insertion.



Insert the needle.



Remove *the needle and insert the tubing*.



Secure the IV.



Intravenous Infusion Calculations

- Drip Rates — is when the infusion volume is calculated into drops.
- The formula for the Drip Rate:
- Drip Rate Drip Rate = Volume (mL) /Time (h) .
- **Example 1**
- A patient is ordered to receive 1 000 mL of intravenous fluids to run over 8 hours. Calculate the drip rate.
- **Solution:** Volume = 1 000 mL. Time = 8 hours.
- Substituting in the formula gives:
- Drip Rate = 1 000 Ml/ 8 h = 125 mL/h .
- Therefore, the patient will receive 125 mL of fluids per 1 hour. Note: When the drip rate is given in minutes, convert the minutes to hours by dividing the required minutes by 60 (since 60 minutes in one hour).

Intravenous Infusion Calculations

- Calculation of drips rates in drops per minute (dpm)

- There are two standard giving sets of drip rates:

- 1. Macro Drop Factor — drop size is normally 20 drops in 1 mL.
- 2. Micro Drop Factor — drop size is normally 60 drops in 1 mL.

- The formula to calculate drip rates in drops per minute (dpm):
- Drip Rate (dpm) = Volume of IV fluid (mL) /Time to run (h) × Drop Factor (drops/mL)/ 60 (min/h)

Intravenous Infusion Calculations

- Example 2
- A patient is to receive 1 L of Hartmann's solution over the next 12 hours. What is the rate of infusion in drops per minute (dpm), if the drop factor is 60 drops per mL .
- Solution: Volume = 1 000 mL, since 1 L = 1 000 mL. Time = 12 hours. Drop Factor = 60 drops per mL.
- Substituting these values into the drip rate formula gives: Drip Rate (dpm) = 1 000 mL/ 12 h × 60 drops/ mL/ 60 min/h = 83.833 ≈ 84 drops/minutes

BLOOD TRANSFUSION



CONTENT

- Definition
- Purposes
- Components of blood Grouping and cross matching
- Type of blood transfusion
- General instructions
- Complications of blood transfusion

DEFINITION

- Blood transfusion is the transfusion of the whole blood or its component such as blood cells or plasma from one person to another person.
- Blood transfusion involves two procedure that is –
- 1)Collection of blood from donor
- 2)Administration of blood to the recipient.

PURPOSES

- To restore the blood volume when there is sudden loss of blood due to hemorrhage.
- To raise the Hb level in cases of severe anemia
- To treat deficiencies of plasma protein, clotting factors or hemophilic globulin etc.
- To provide antibodies to those persons who are sick and having lowered immunity.
- To replace the blood with hemolytic agents with fresh blood
- To improve the leukocyte count in blood as in agranulocytosis.
- To combat infection in leucopenia

COMPONENTS OF BLOOD (FOR TRANSFUSION)

- Each unit of blood is tested for evidence of hepatitis-b, hepatitis-c, human immuno deficiency virus I&II and syphilis.
-
- The blood is then processed into sub-components.

- These are- 1)Whole blood
  2) Packed cell volume
  3) Fresh frozen plasma
  4) Platelets
  5) Cryoprecipitate

COMPONENTS OF BLOOD (FOR TRANSFUSION)

- Whole blood :-Whole blood is unseparated blood containing an anticoagulant – preservative solution.

One unit of whole blood contains-

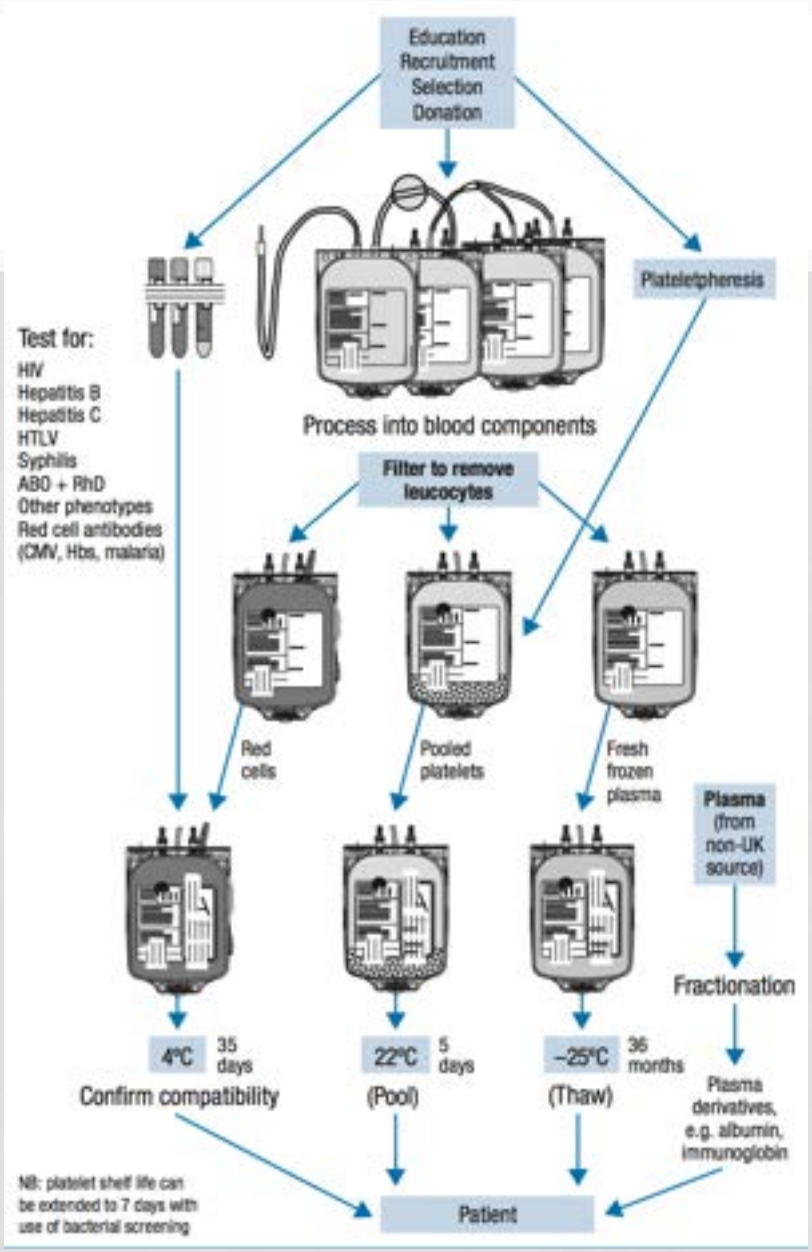
1. 450 ml of donor blood.
2. 50 ml of anticoagulant-preservative solution.
3. Hemoglobin approx.12g/ml & haematocrit 35%- 45%.
4. No functional platelets.

- Stored between +2 and +6 degrees centigrade in a blood bank refrigerator.

- Transfusion should be started within 30 minutes of removal from the refrigerator and completed within 4 hours of commencement because changes in the composition may occur due to red cell metabolism

COMPONENTS OF BLOOD (FOR TRANSFUSION)

1. Packed Red Cells:- Packed red cells are cells that are spun down and concentrated. One unit of packed red cells is approx. 330 ml and has a haematocrit of 50-70%. They are stored in a SAG-M (saline-adenine- glucose-mannitol) solution to increase their shelf life to 5weeks at 2-6degrees centigrade.
2. Fresh frozen plasma . Fresh frozen plasma is rich in coagulation factors. It is separated from whole blood and stored at-40 to -50 degrees centigrade with a 2year shelf-life. It is the first line therapy in the treatment of coagulopathic haemorrhage


Education
Recruitment
Selection
Donation
Plateletpheresis
Test for:
HIV
Hepatitis B
Hepatitis C
HTLV
Syphilis
ABO + RhD
Other phenotypes
Red cell antibodies
(CMV, Hbs, malaria)
Process into blood components
Filter to remove leucocytes
Red cells
Pooled platelets
Fresh frozen plasma
Plasma (from non-UK source)
Fractionation
4°C 35 days
22°C 5 days
−25°C 36 months
Confirm compatibility
(Pool)
(Thaw)
Plasma derivatives, e.g. albumin, immunoglobin
NB: platelet shelf life can be extended to 7 days with use of bacterial screening
Patient

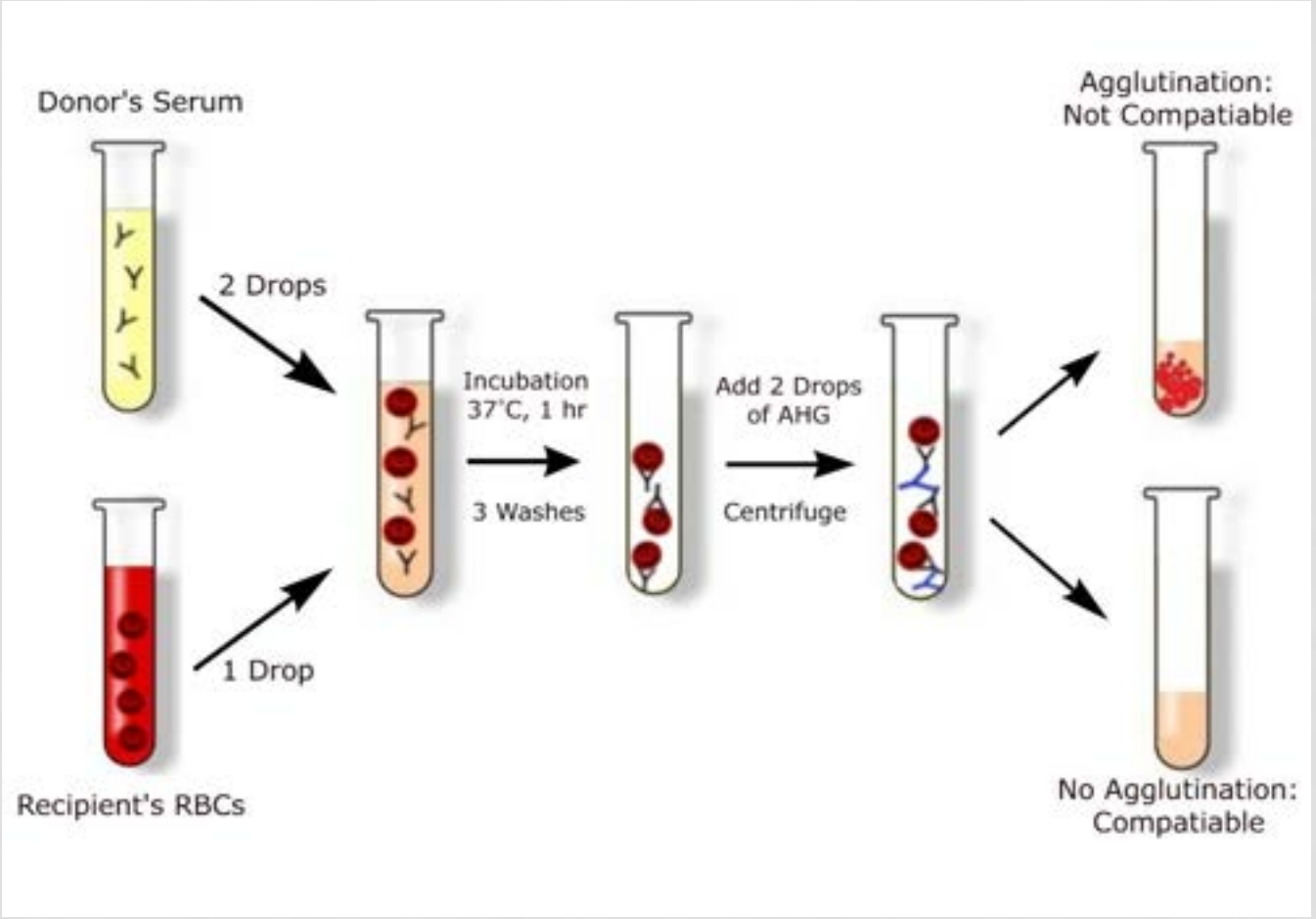
COMPONENTS OF BLOOD (FOR TRANSFUSION

- Cryoprecipitate:- Cryoprecipitate is a supernatant precipitate of fresh frozen plasma and is rich in factor VIII and fibrinogen.
- It is stored at -30 degrees centigrade with a 2 years shelf life. Indicated in low fibrinogen states (<1g/l) or in cases of factor VIII deficiency (hemophilia-a), von will brand's disease and as a source of fibrinogen in disseminated intravascular coagulation
- Pooled units containing 3-6 gms fibrinogen in 200-500 ml raises the fibrinogen level by approx. 1g/L. Must be infused within 6 hours

BLOOD GROUPING AND CROSS MATCHING

1. Each person has one of the following blood types: A, B, AB, or O.
2. O can be given to anyone but can only receive O.
3. AB can receive any type but can only be given to AB.
4. Also, every person's blood is either Rh-positive or Rh-negative.
5. The blood used in a transfusion must be compatible with the patient's blood type.
6. Type O blood is called the universal donor
7. People with type AB blood are called universal recipients
8. People with Rh-positive blood can get Rh-positive or Rh-negative blood. But people with Rh-negative blood should get only Rh-negative blood.

CROSS MATCHING



TYPE OF BLOOD TRANSFUSION

- Allogenic blood transfusion (someone else blood)
- Autogenic blood transfusion (own blood)
- Exchange blood transfusion

GENERAL INSTRUCTION

General instruction Regarding-

1. Selection of donor
2. Collection, storage and transportation of the blood
3. Administration of blood to the recipient

SELECTION OF DONOR

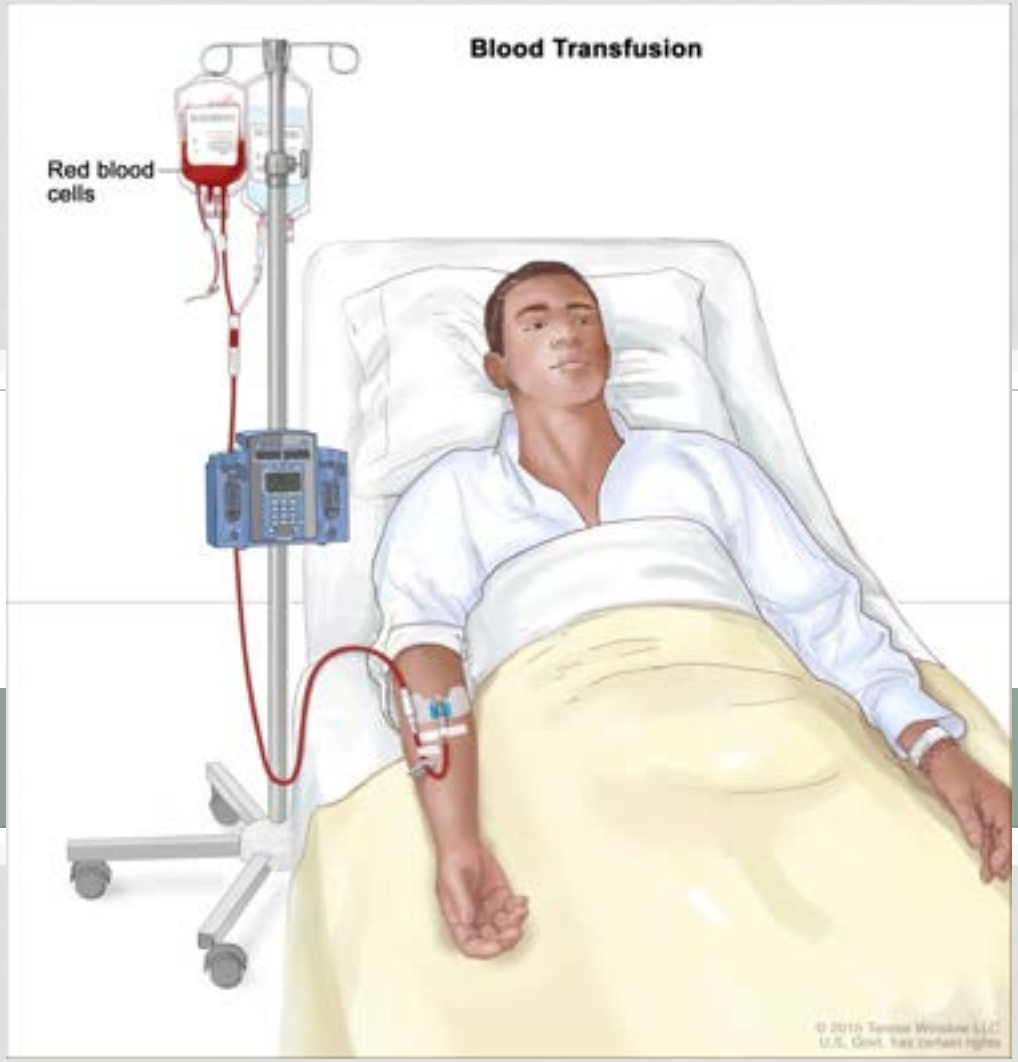
1. Donor should be free from diseases such as TB, cancer, jaundice or any other transmissible disease.
2. Make sure that donor has not donated the blood within previous 90 days.
3. Physically active, between the age of 18 to 65 years with an average height and weight
4. Donor must have normal vital signs
5. Must not have been pregnant within the last 6 months

SELECTION OF DONOR

- Hb level must be above 12gm%
- Donor should be disqualified who have history of recent dental surgery, major surgery, receipt of blood or blood component, immunization etc.
- Explain the procedure to the donor
- Blood should not be collected empty stomach, should not be dehydrated. ⊠ Following the donation donor should be offered sweetened drink and asked to take rest at least for 1-2 hrs. to prevent fain

COLLECTION, STORAGE AND TRANSPORTATION OF BLOOD

- Donor's blood immediately after it is withdrawn should be placed in the refrigerator.
- Stored blood should be inspected daily and before use for evidence of hemolysis or bacterial contamination
- The transportation of blood in the hospital should be done within 30 minutes after it is taken from the place of storage.
- If the blood is kept at room temperature the temperature of blood will rise above 10 degree C in 30 minutes.
- If blood is not used it should be returned to the refrigerator within half an hour
- When blood is transported to distant place use precooled insulated bags to keep the temperature of blood below 10 degree C


Blood Transfusion
Red blood cells

COLLECTION, STORAGE AND TRANSPORTATION OF BLOOD

- Collection of blood from the donor is done in laboratory by laboratory technician.
- Donor's blood is collected in a sterile container containing anticoagulant solution (ACD)
- All the articles used for the collection of blood must be sterile
- Each donor unit must be labeled clear readable letters i.e.- name, donor no. ABO grouping, Rh typing, date of drawing, date of expiry and result of tests for hepatitis, and syphilis

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

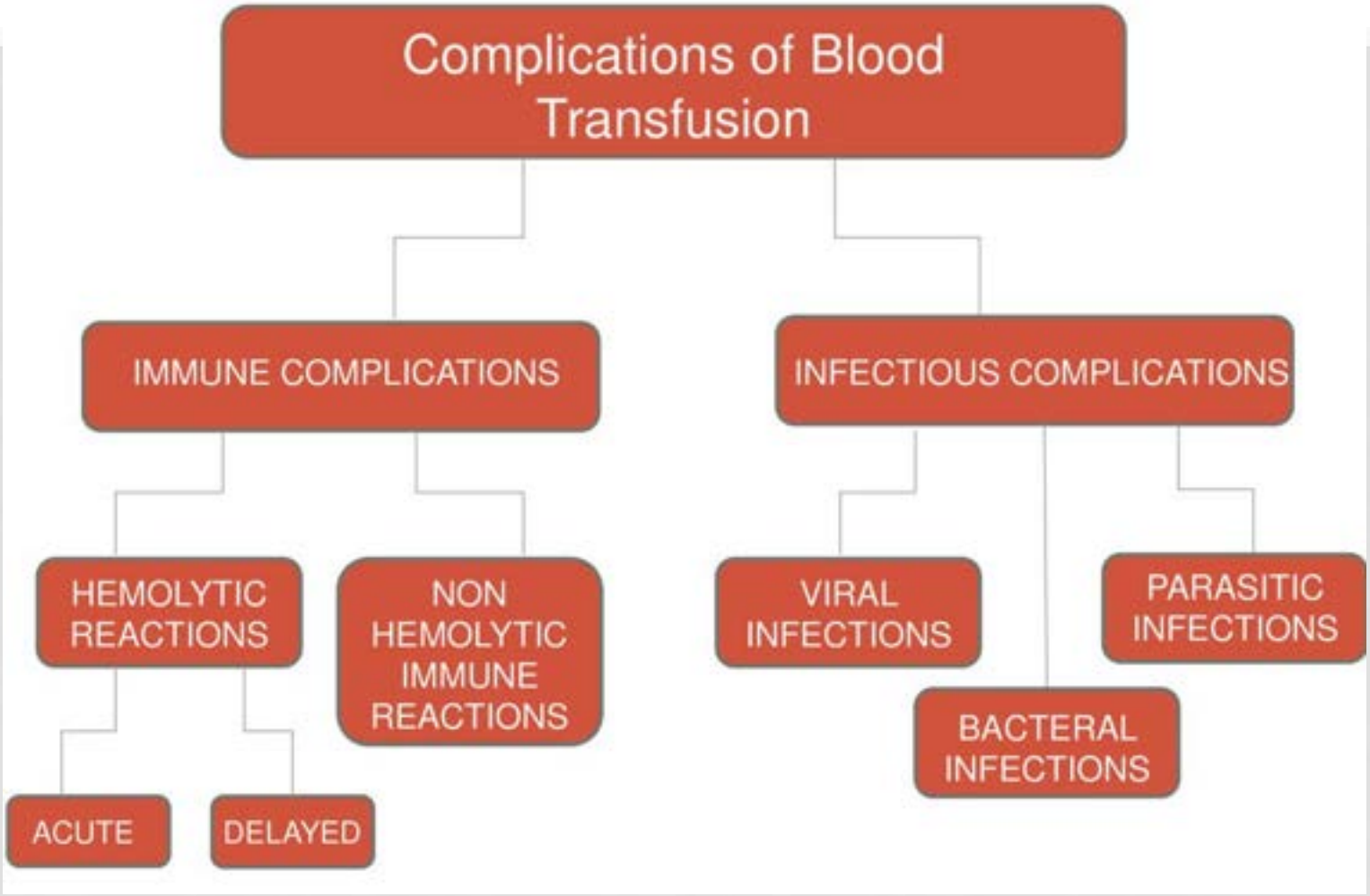
- When sending the recipient's blood sample for grouping and cross matching, it must be clearly labeled with name, IP number, bed number, ward no.
- Fresh sample taken within four hrs. should be used for typing and cross matching
- A request form should accompany with blood sample and form should contain- name, IP no. bed no. ward no. name of the physician, exact amount of blood component required, diagnosis of the patient, any blood transfusion given earlier, if so, the group and type of blood administered any reaction observed

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

- It is essential that the physician writes all orders for typing, cross matching and administration of whole blood or blood products.
- Prior to administration of blood two registered nurse or a physician and a registered nurse should verify all informations on the report of the cross match, unit label, and the patient's identifications. If there is any discrepancies the unit should be returned to the blood bank with remarks.
- Whole blood or blood should be transfused through an appropriate, sterile transfusion set containing a filter.
- Transfusion set should be free from air
- Use 18 gauge needle for transfusion
- No medications or other additives should be given the same IV route or should not be mixed with blood

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

1. Keep the patient warm and comfortable if necessary.
2. Offer bedpan before starting the procedure and as necessary.
3. Record the amount of blood, type and group, rate of flow, any reaction and any medication administered
4. If IV infusion is to be given before, after or during the transfusion always use the normal saline.
5. Prior to transfusion record the vital signs of the patient to provide the baseline for further observation.
6. Adjust the rate of flow to 5-10 ml per minute during the first 30 minutes of transfusion to detect any complications as early as possible.
7. Allow the blood to remain at room temperature prior to administration of blood
8. Watch for any complications throughout the procedure


Complications of Blood Transfusion
IMMUNE COMPLICATIONS
INFECTIOUS COMPLICATIONS
HEMOLYTIC REACTIONS
NON HEMOLYTIC IMMUNE REACTIONS
VIRAL INFECTIONS
PARASITIC INFECTIONS
BACTERAL INFECTIONS
ACUTE
DELAYED

COMPLICATION OF BLOOD TRANSFUSIONS

- Definition- Blood transfusion reaction is a systemic response by the body to blood incompatible with that of recipient It is mainly caused due to-
- ABO incompatibility
- Allergic reactions to the WBCs, platelets, or plasma protein components of the transfused blood
- Potassium or citrate preservative in the blood

- Acute hemolytic transfusion reaction
- Delayed hemolytic transfusion reaction
- Pyrogenic reaction
- Allergic reaction
- Anaphylactic reaction
- Transmission of infectious diseases
- Circulatory overload
- Hyperkalemia
- Hypocalcemia
- Haemosiderosis
- Infiltration and Hematoma
- Thrombophlebitis
- Pulmonary embolism

ACUTE HEMOLYTIC TRANSFUSION REACTION

- Develops during the first 5-15 minutes.
- In hemolytic transfusion reaction circulating RBCs are ruptured with the release of hemoglobin
- Causes of acute hemolytic reaction-
- ABO incompatibility
- Rh incompatibility
- Improper storage of blood
- Uncontrolled refrigeration of blood resulting in freezing
- Storage beyond 21 days limit
- Warming of blood above 40 degree C
- Exposure of blood to dextrose solutions.

- Clinical features of acute hemolytic reaction-
- Onset of fever
- Chills, headache, dyspnea, cynosis, chest pain
- Nausea, vomiting
- Increased heart rate and respiratory rate
- Hemoglobinuria
- Complications include- Hypotension followed by shock Oliguria then anuria followed by renal failure

- **Nursing management of acute hemolytic reaction-**
- Closely observe the patient for the first ten minutes of the transfusion.
- Since these reactions occur very rapidly, the rate of flow should be minimal.
- Discontinue the transfusion immediately when reaction is assessed.
- Inform the physician and implement the treatment as prescribed by the physician.
- Inform the laboratory to do the cross matching and grouping of the blood.
- Maintain IV infusion with 5% glucose or saline using a new IV set.
- Large quantities of fluid is given to promote diuresis and counteract shock.
- Monitor vital sign every 15 min. to assess shock and collapse.
- Record fluid intake and output to assess the kidney function
- Oxygen inhalation is given to relieve dyspnea

MEDICAL MANAGEMENT OF ACUTE HEMOLYTIC REACTION-

- Large quantities of fluids
- Mannitol
- Heparinization
- Oxygen and adrenaline
- Sedation
- Blood transfusion
- Hemodialysis

DELAYED HEMOLYTIC TRANSFUSION REACTION

- Occurs due to incompatibility of RBC antigens other than ABO group
- It develops days to weeks after transfusion
- It is featured by persistent decrease in Hb level and low grade fever
- Many time this reaction is missed, if known inform the physician and blood blank

PYROGENIC REACTIONS

It develops immediately or within 6 hrs of infusion.

It results from pyrogenic substances from the tubings

Causes of pyrogenic reactions-

Improper preparation of donor's site

Not following proper aseptic technique

Antigen and antibody reactions to WBCs and platelets contained in blood product.

Improper refrigeration

Clinical features-

Fever with chills

Nausea, vomiting and diarrhea

Headache

Backache

Delirium, shock and renal failure

Prevention- Proper screening of donor

Use of disposable and pyrogen free sterile syringes and tubing for collecting and transfusing the blood.

Proper technique for storing the blood

ALLERGIC REACTION

- It develops any time or within one hour of transfusion
- Allergic reactions are the result of sensitivity of the individual to the plasma protein in the transfused blood.
- It is characterized by itching, rashes, laryngeal edema and bronchial spasm in severe cases.
- Treatment normally include injections of antihistamines and corticosteroids as necessary.

ANAPHYLACTIC REACTIONS

- Extremely rare but life threatening develops immediately after transfusion of few mL of blood
- It is caused by idiosyncratic reaction in clients with IgA deficiency.
- It is characterized by sever cardio-respiratory features such as- dyspnea, cyanosis, tachypnea, tachycardia, hypotension and collapse.
- Immediately transfusion is stopped and inform to physician and resuscitative measures are started
- Monitor the vital signs every 15. min until patient recovers

CIRCULATORY OVERLOAD-

Giving whole blood to patient with severe anemia is very dangerous as patient require the RBCs not the other component of blood and may develop circulatory overload

Condition of heart failure may also cause the circulatory overload with blood transfusion.

- Use packed RBCs instead of whole blood
- Administer diuretics prior to blood transfusion to reduce the plasma volume
- Transfuse the blood at a slow rate
- Check the patient's pulse at every 15 minutes.
- Check the patient's neck vein for fullness
- Observe the CVP, if it is greater than 10 cm of water indicates circulatory overload
- Observe for the signs of respiratory distress
- Give minimum quantity of blood at a time
- Stop the transfusion and inform to the physician if patient develops the sign and symptoms of circulatory overload.

HYPERKALEMIA-

- Stored blood may cause hyperkalemia
- Blood that is one day old has plasma potassium content approximately 7mEq/litre and 21 days old blood contains about 23mEq/litre.

HYPOCALCEMIA-

- It develops due to citrate toxicity.
- During massive transfusion citrate in the blood combines with ionized calcium and tetany may result.
- Higher level of citrate may cause cardiac arrest.
- Treatment consist of administration of calcium gluconate to prevent or eliminate the toxic effects by neutralizing the acidosis

HEMOSIDEROSIS

- It is also known as iron over load
- It may develop in clients receiving frequent blood transfusion.
- Hemosiderosis is an abnormal deposition of iron in various tissues in the form of hemosiderin which is an iron rich pigment that is the product of hemolysis

OTHER COMPLICATIONS-

- Infiltration and hematoma at the site of the needle
- Thrombophlebitis
- Pulmonary embolism

NURSING MANAGEMENT REGARDING COMPLICATIONS OF BLOOD TRANSFUSION

- Stop the transfusion immediately
- Notify the physician
- Connect the IV line with 0.9% normal saline
- Be with the client, observe the sign and symptoms and monitor the vital signs till they become stable
- Get ready the emergency drugs such as vasopressors, antihistamine, steroids, and fluids
- Prepare for CPR
- Obtain a urine specimen and send to the laboratory
- Save the blood container and tubing for return to the bank
- Document the reactions and measures carried out.

BLOOD TRANSFUSION



CONTENT

- Definition
- Purposes
- Components of blood Grouping and cross matching
- Type of blood transfusion
- General instructions
- Complications of blood transfusion

DEFINITION

- Blood transfusion is the transfusion of the whole blood or its component such as blood cells or plasma from one person to another person.
- Blood transfusion involves two procedure that is –
- 1)Collection of blood from donor
- 2)Administration of blood to the recipient.

PURPOSES

- To restore the blood volume when there is sudden loss of blood due to hemorrhage.
- To raise the Hb level in cases of severe anemia
- To treat deficiencies of plasma protein, clotting factors or hemophilic globulin etc.
- To provide antibodies to those persons who are sick and having lowered immunity.
- To replace the blood with hemolytic agents with fresh blood
- To improve the leukocyte count in blood as in agranulocytosis.
- To combat infection in leucopenia

COMPONENTS OF BLOOD (FOR TRANSFUSION)

- Each unit of blood is tested for evidence of hepatitis-b, hepatitis-c, human immuno deficiency virus I&II and syphilis.
-
- The blood is then processed into sub-components.

- These are- 1)Whole blood
  2) Packed cell volume
  3) Fresh frozen plasma
  4) Platelets
  5) Cryoprecipitate

COMPONENTS OF BLOOD (FOR TRANSFUSION)

- Whole blood :-Whole blood is unseparated blood containing an anticoagulant – preservative solution.

One unit of whole blood contains-

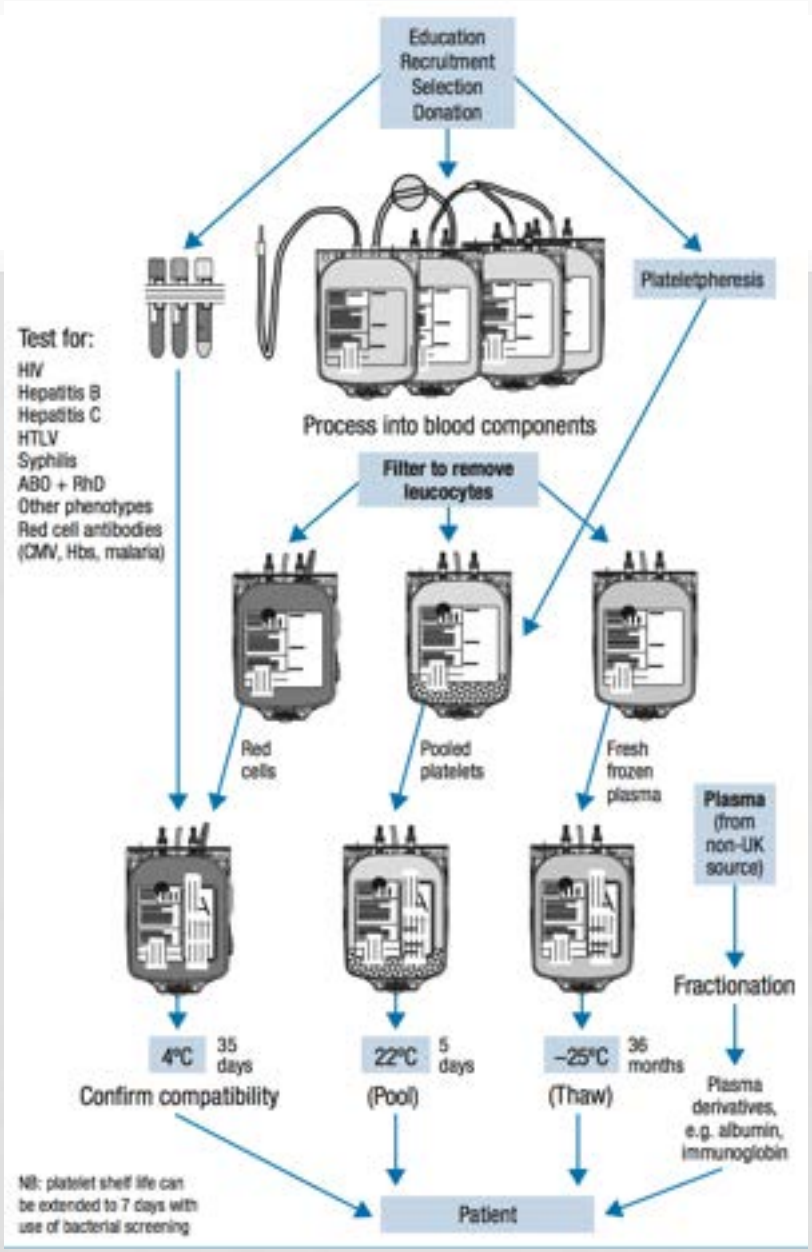
1. 450 ml of donor blood.
2. 50 ml of anticoagulant-preservative solution.
3. Hemoglobin approx.12g/ml & haematocrit 35%- 45%.
4. No functional platelets.

- Stored between +2 and +6 degrees centigrade in a blood bank refrigerator.

- Transfusion should be started within 30 minutes of removal from the refrigerator and completed within 4 hours of commencement because changes in the composition may occur due to red cell metabolism

COMPONENTS OF BLOOD (FOR TRANSFUSION)

1. Packed Red Cells:- Packed red cells are cells that are spun down and concentrated. One unit of packed red cells is approx. 330 ml and has a haematocrit of 50-70%. They are stored in a SAG-M (saline-adenine- glucose-mannitol) solution to increase their shelf life to 5weeks at 2-6degrees centigrade.
2. Fresh frozen plasma . Fresh frozen plasma is rich in coagulation factors. It is separated from whole blood and stored at-40 to -50 degrees centigrade with a 2year shelf-life. It is the first line therapy in the treatment of coagulopathic haemorrhage


Education
Recruitment
Selection
Donation
Plateletpheresis
Test for:
HIV
Hepatitis B
Hepatitis C
HTLV
Syphilis
ABO + RhD
Other phenotypes
Red cell antibodies
(CMV, Hbs, malaria)
Process into blood components
Filter to remove leucocytes
Red cells
Pooled platelets
Fresh frozen plasma
Plasma (from non-UK source)
Fractionation
4°C 35 days
22°C 5 days
−25°C 36 months
Confirm compatibility
(Pool)
(Thaw)
Plasma derivatives, e.g. albumin, immunoglobin
NB: platelet shelf life can be extended to 7 days with use of bacterial screening
Patient

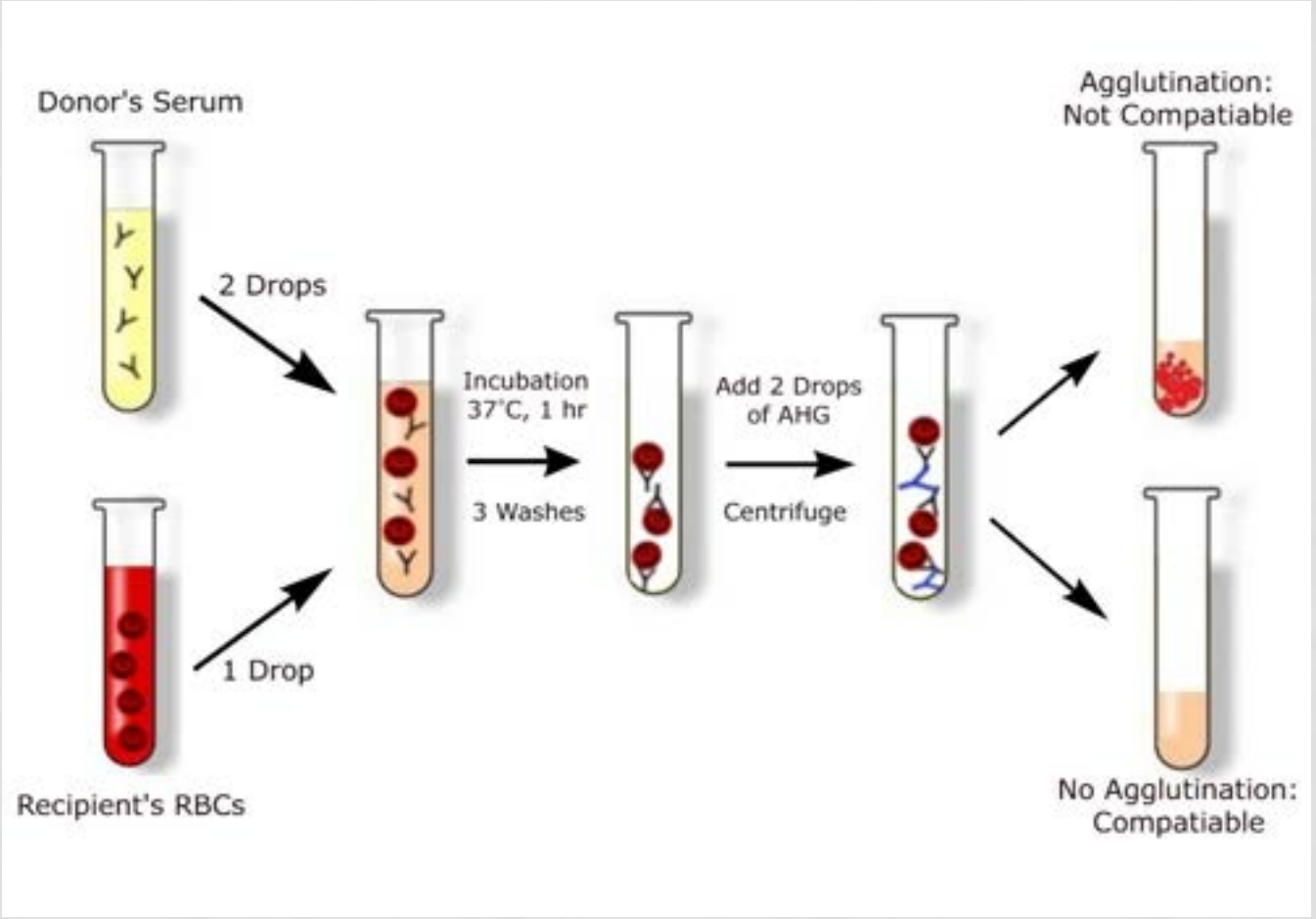
COMPONENTS OF BLOOD (FOR TRANSFUSION

- Cryoprecipitate:- Cryoprecipitate is a supernatant precipitate of fresh frozen plasma and is rich in factor VIII and fibrinogen.
- It is stored at -30 degrees centigrade with a 2 years shelf life. Indicated in low fibrinogen states (<1g/l) or in cases of factor VIII deficiency (hemophilia-a), von will brand's disease and as a source of fibrinogen in disseminated intravascular coagulation
- Pooled units containing 3-6 gms fibrinogen in 200-500 ml raises the fibrinogen level by approx. 1g/L. Must be infused within 6 hours

BLOOD GROUPING AND CROSS MATCHING

1. Each person has one of the following blood types: A, B, AB, or O.
2. O can be given to anyone but can only receive O.
3. AB can receive any type but can only be given to AB.
4. Also, every person's blood is either Rh-positive or Rh-negative.
5. The blood used in a transfusion must be compatible with the patient's blood type.
6. Type O blood is called the universal donor
7. People with type AB blood are called universal recipients
8. People with Rh-positive blood can get Rh-positive or Rh-negative blood. But people with Rh-negative blood should get only Rh-negative blood.

CROSS MATCHING



TYPE OF BLOOD TRANSFUSION

- Allogenic blood transfusion (someone else blood)
- Autogenic blood transfusion (own blood)
- Exchange blood transfusion

GENERAL INSTRUCTION

General instruction Regarding-

1. Selection of donor
2. Collection, storage and transportation of the blood
3. Administration of blood to the recipient

SELECTION OF DONOR

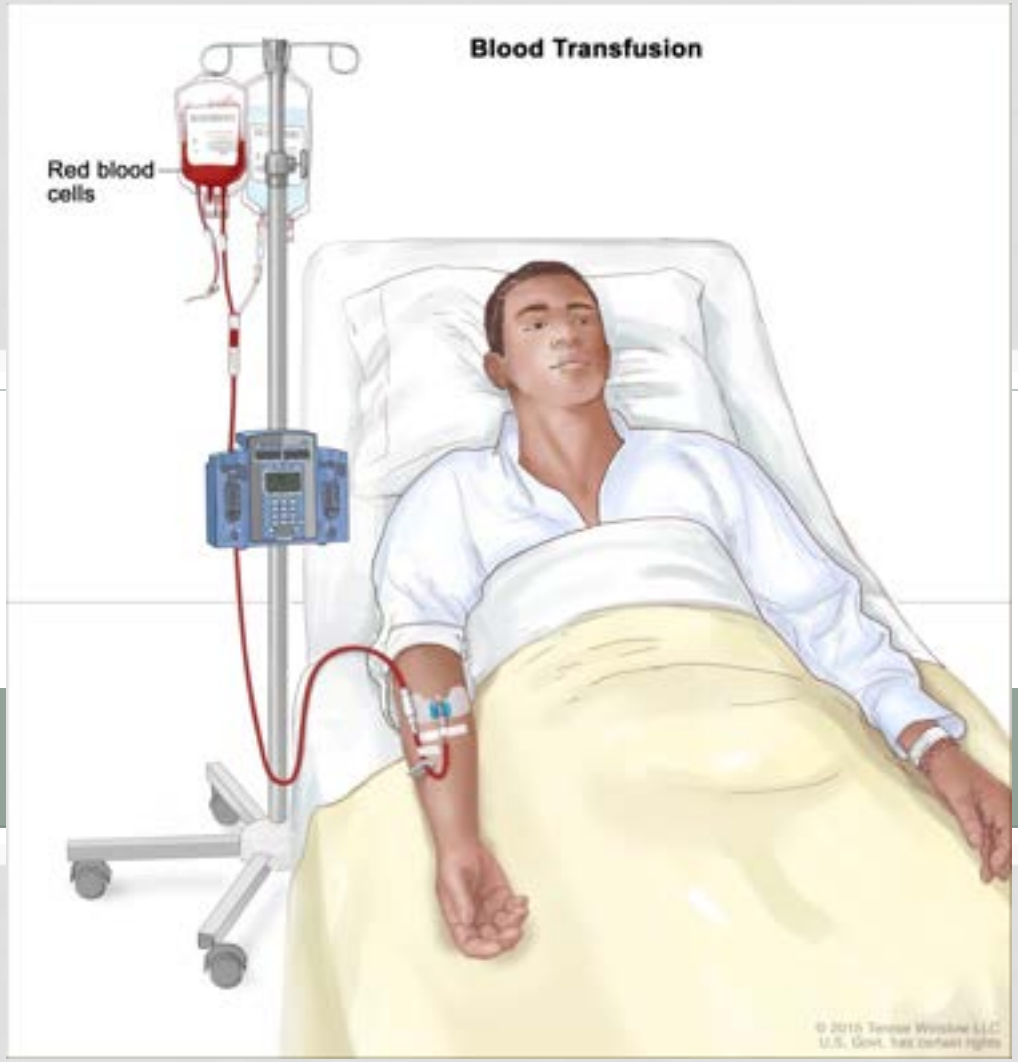
1. Donor should be free from diseases such as TB, cancer, jaundice or any other transmissible disease.
2. Make sure that donor has not donated the blood within previous 90 days.
3. Physically active, between the age of 18 to 65 years with an average height and weight
4. Donor must have normal vital signs
5. Must not have been pregnant within the last 6 months

SELECTION OF DONOR

- Hb level must be above 12gm%
- Donor should be disqualified who have history of recent dental surgery, major surgery, receipt of blood or blood component, immunization etc.
- Explain the procedure to the donor
- Blood should not be collected empty stomach, should not be dehydrated. ⊠ Following the donation donor should be offered sweetened drink and asked to take rest at least for 1-2 hrs. to prevent fain

COLLECTION, STORAGE AND TRANSPORTATION OF BLOOD

- Donor's blood immediately after it is withdrawn should be placed in the refrigerator.
- Stored blood should be inspected daily and before use for evidence of hemolysis or bacterial contamination
- The transportation of blood in the hospital should be done within 30 minutes after it is taken from the place of storage.
- If the blood is kept at room temperature the temperature of blood will rise above 10 degree C in 30 minutes.
- If blood is not used it should be returned to the refrigerator within half an hour
- When blood is transported to distant place use precooled insulated bags to keep the temperature of blood below 10 degree C


Blood Transfusion
Red blood cells

COLLECTION, STORAGE AND TRANSPORTATION OF BLOOD

- Collection of blood from the donor is done in laboratory by laboratory technician.
- Donor's blood is collected in a sterile container containing anticoagulant solution (ACD)
- All the articles used for the collection of blood must be sterile
- Each donor unit must be labeled clear readable letters i.e.- name, donor no. ABO grouping, Rh typing, date of drawing, date of expiry and result of tests for hepatitis, and syphilis

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

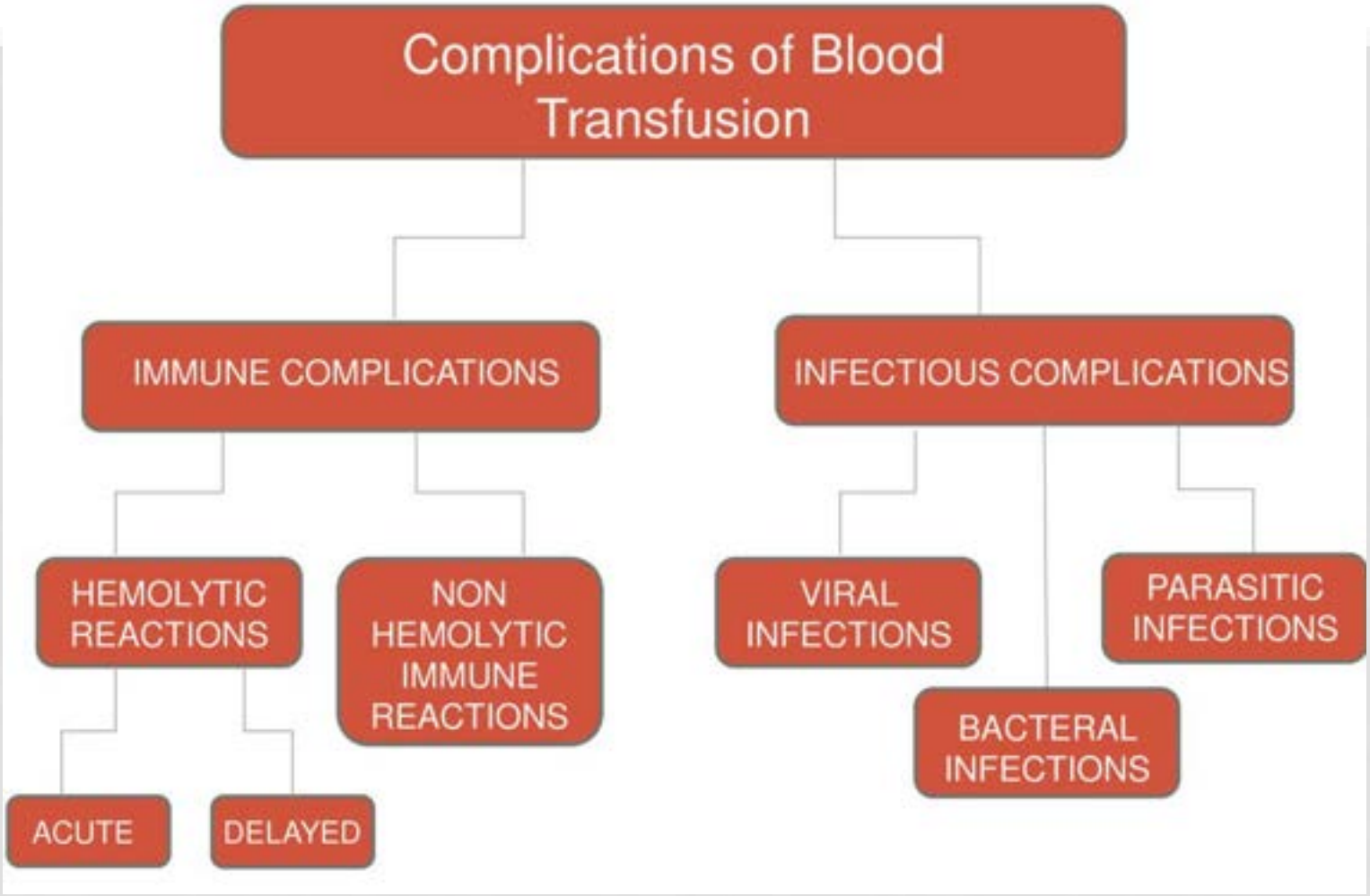
- When sending the recipient's blood sample for grouping and cross matching, it must be clearly labeled with name, IP number, bed number, ward no.
- Fresh sample taken within four hrs. should be used for typing and cross matching
- A request form should accompany with blood sample and form should contain- name, IP no. bed no. ward no. name of the physician, exact amount of blood component required, diagnosis of the patient, any blood transfusion given earlier, if so, the group and type of blood administered any reaction observed

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

- It is essential that the physician writes all orders for typing, cross matching and administration of whole blood or blood products.
- Prior to administration of blood two registered nurse or a physician and a registered nurse should verify all informations on the report of the cross match, unit label, and the patient's identifications. If there is any discrepancies the unit should be returned to the blood bank with remarks.
- Whole blood or blood should be transfused through an appropriate, sterile transfusion set containing a filter.
- Transfusion set should be free from air
- Use 18 gauge needle for transfusion
- No medications or other additives should be given the same IV route or should not be mixed with blood

ADMINISTRATION OF THE BLOOD TO THE RECIPIENT

1. Keep the patient warm and comfortable if necessary.
2. Offer bedpan before starting the procedure and as necessary.
3. Record the amount of blood, type and group, rate of flow, any reaction and any medication administered
4. If IV infusion is to be given before, after or during the transfusion always use the normal saline.
5. Prior to transfusion record the vital signs of the patient to provide the baseline for further observation.
6. Adjust the rate of flow to 5-10 ml per minute during the first 30 minutes of transfusion to detect any complications as early as possible.
7. Allow the blood to remain at room temperature prior to administration of blood
8. Watch for any complications throughout the procedure


Complications of Blood Transfusion
IMMUNE COMPLICATIONS
INFECTIOUS COMPLICATIONS
HEMOLYTIC REACTIONS
NON HEMOLYTIC IMMUNE REACTIONS
VIRAL INFECTIONS
PARASITIC INFECTIONS
BACTERAL INFECTIONS
ACUTE
DELAYED

COMPLICATION OF BLOOD TRANSFUSIONS

- Definition- Blood transfusion reaction is a systemic response by the body to blood incompatible with that of recipient It is mainly caused due to-
- ABO incompatibility
- Allergic reactions to the WBCs, platelets, or plasma protein components of the transfused blood
- Potassium or citrate preservative in the blood

- Acute hemolytic transfusion reaction
- Delayed hemolytic transfusion reaction
- Pyrogenic reaction
- Allergic reaction
- Anaphylactic reaction
- Transmission of infectious diseases
- Circulatory overload
- Hyperkalemia
- Hypocalcemia
- Haemosiderosis
- Infiltration and Hematoma
- Thrombophlebitis
- Pulmonary embolism

ACUTE HEMOLYTIC TRANSFUSION REACTION

- Develops during the first 5-15 minutes.
- In hemolytic transfusion reaction circulating RBCs are ruptured with the release of hemoglobin
- Causes of acute hemolytic reaction-
- ABO incompatibility
- Rh incompatibility
- Improper storage of blood
- Uncontrolled refrigeration of blood resulting in freezing
- Storage beyond 21 days limit
- Warming of blood above 40 degree C
- Exposure of blood to dextrose solutions.

- Clinical features of acute hemolytic reaction-
- Onset of fever
- Chills, headache, dyspnea, cynosis, chest pain
- Nausea, vomiting
- Increased heart rate and respiratory rate
- Hemoglobinuria
- Complications include- Hypotension followed by shock Oliguria then anuria followed by renal failure

- **Nursing management of acute hemolytic reaction-**
- Closely observe the patient for the first ten minutes of the transfusion.
- Since these reactions occur very rapidly, the rate of flow should be minimal.
- Discontinue the transfusion immediately when reaction is assessed.
- Inform the physician and implement the treatment as prescribed by the physician.
- Inform the laboratory to do the cross matching and grouping of the blood.
- Maintain IV infusion with 5% glucose or saline using a new IV set.
- Large quantities of fluid is given to promote diuresis and counteract shock.
- Monitor vital sign every 15 min. to assess shock and collapse.
- Record fluid intake and output to assess the kidney function
- Oxygen inhalation is given to relieve dyspnea

MEDICAL MANAGEMENT OF ACUTE HEMOLYTIC REACTION-

- Large quantities of fluids
- Mannitol
- Heparinization
- Oxygen and adrenaline
- Sedation
- Blood transfusion
- Hemodialysis

DELAYED HEMOLYTIC TRANSFUSION REACTION

- Occurs due to incompatibility of RBC antigens other than ABO group
- It develops days to weeks after transfusion
- It is featured by persistent decrease in Hb level and low grade fever
- Many time this reaction is missed, if known inform the physician and blood blank

PYROGENIC REACTIONS

It develops immediately or within 6 hrs of infusion.

It results from pyrogenic substances from the tubings

Causes of pyrogenic reactions-

Improper preparation of donor's site

Not following proper aseptic technique

Antigen and antibody reactions to WBCs and platelets contained in blood product.

Improper refrigeration

Clinical features-

Fever with chills

Nausea, vomiting and diarrhea

Headache

Backache

Delirium, shock and renal failure

Prevention- Proper screening of donor

Use of disposable and pyrogen free sterile syringes and tubing for collecting and transfusing the blood.

Proper technique for storing the blood

ALLERGIC REACTION

- It develops any time or within one hour of transfusion
- Allergic reactions are the result of sensitivity of the individual to the plasma protein in the transfused blood.
- It is characterized by itching, rashes, laryngeal edema and bronchial spasm in severe cases.
- Treatment normally include injections of antihistamines and corticosteroids as necessary.

ANAPHYLACTIC REACTIONS

- Extremely rare but life threatening develops immediately after transfusion of few mL of blood
- It is caused by idiosyncratic reaction in clients with IgA deficiency.
- It is characterized by sever cardio-respiratory features such as- dyspnea, cyanosis, tachypnea, tachycardia, hypotension and collapse.
- Immediately transfusion is stopped and inform to physician and resuscitative measures are started
- Monitor the vital signs every 15. min until patient recovers

CIRCULATORY OVERLOAD-

Giving whole blood to patient with severe anemia is very dangerous as patient require the RBCs not the other component of blood and may develop circulatory overload

Condition of heart failure may also cause the circulatory overload with blood transfusion.

- Use packed RBCs instead of whole blood
- Administer diuretics prior to blood transfusion to reduce the plasma volume
- Transfuse the blood at a slow rate
- Check the patient's pulse at every 15 minutes.
- Check the patient's neck vein for fullness
- Observe the CVP, if it is greater than 10 cm of water indicates circulatory overload
- Observe for the signs of respiratory distress
- Give minimum quantity of blood at a time
- Stop the transfusion and inform to the physician if patient develops the sign and symptoms of circulatory overload.

HYPERKALEMIA-

- Stored blood may cause hyperkalemia
- Blood that is one day old has plasma potassium content approximately 7mEq/litre and 21 days old blood contains about 23mEq/litre.

HYPOCALCEMIA-

- It develops due to citrate toxicity.
- During massive transfusion citrate in the blood combines with ionized calcium and tetany may result.
- Higher level of citrate may cause cardiac arrest.
- Treatment consist of administration of calcium gluconate to prevent or eliminate the toxic effects by neutralizing the acidosis

HEMOSIDEROSIS

- It is also known as iron over load
- It may develop in clients receiving frequent blood transfusion.
- Hemosiderosis is an abnormal deposition of iron in various tissues in the form of hemosiderin which is an iron rich pigment that is the product of hemolysis

OTHER COMPLICATIONS-

- Infiltration and hematoma at the site of the needle
- Thrombophlebitis
- Pulmonary embolism

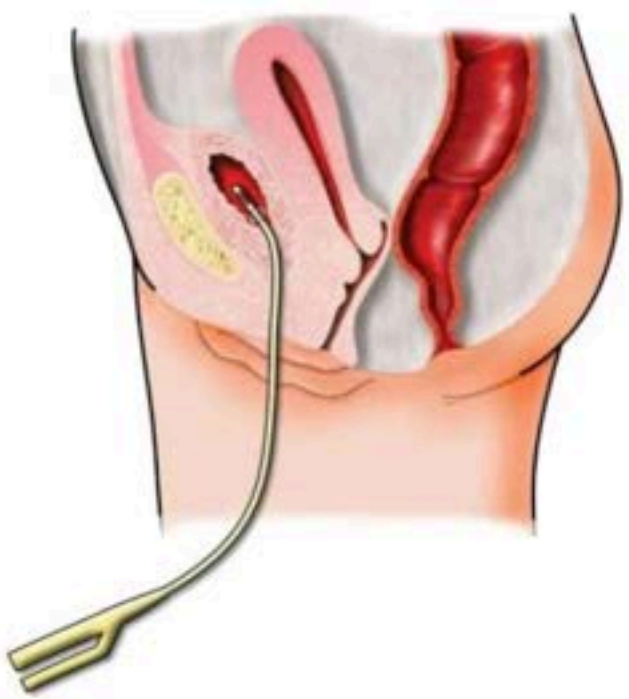
NURSING MANAGEMENT REGARDING COMPLICATIONS OF BLOOD TRANSFUSION

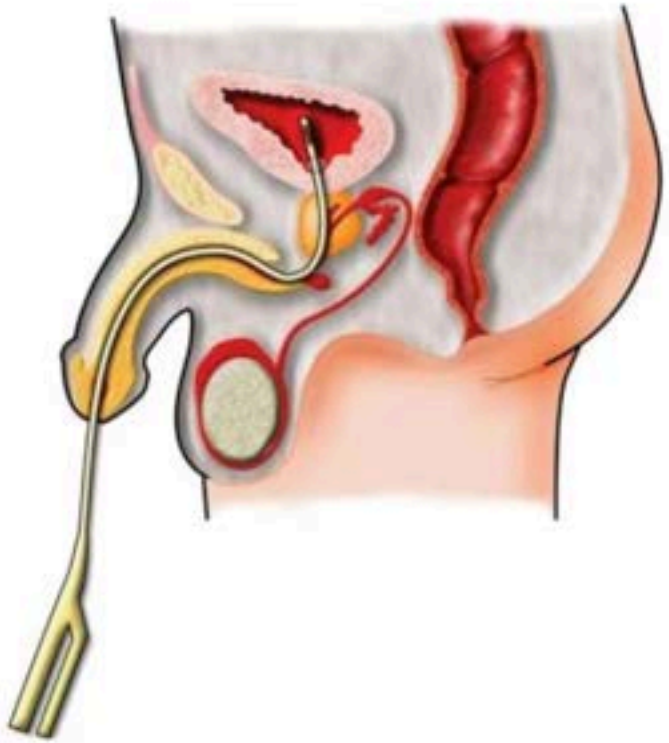
- Stop the transfusion immediately
- Notify the physician
- Connect the IV line with 0.9% normal saline
- Be with the client, observe the sign and symptoms and monitor the vital signs till they become stable
- Get ready the emergency drugs such as vasopressors, antihistamine, steroids, and fluids
- Prepare for CPR
- Obtain a urine specimen and send to the laboratory
- Save the blood container and tubing for return to the bank
- Document the reactions and measures carried out.

URINARY CATHETERIZATION



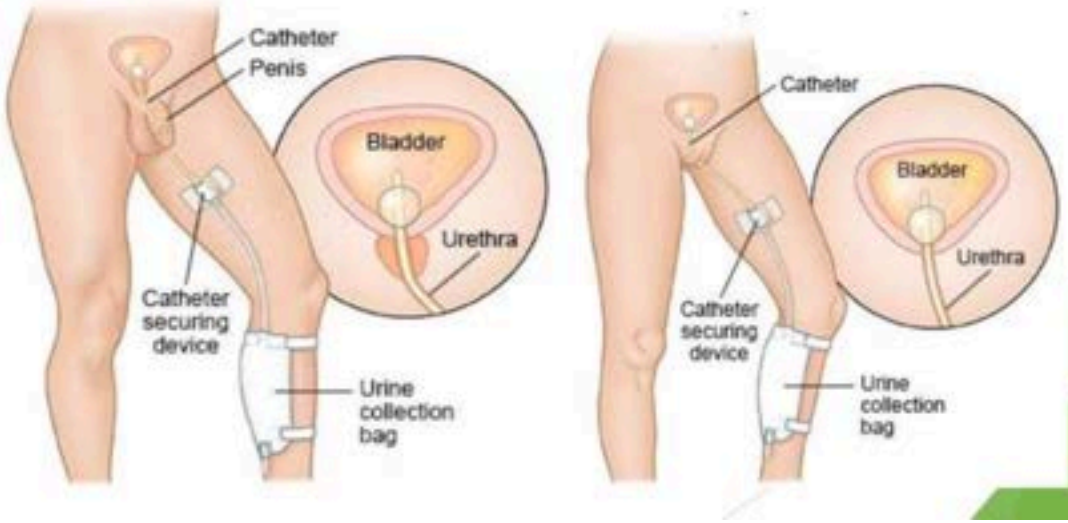
Presented by
Dr. Hetvi Vaidya





DEFINITION

Catheterization of the urinary bladder is the insertion of a hollow tube through the urethra into the bladder for removing urine. It is an aseptic procedure for which sterile equipment is required.



PURPOSES OF URINARY CATHETERIZATION

a. Relieve Urinary Retention.

b. Obtain a Sterile Urine Specimen from a Female Patient.

c. Measure Residual Urine.

d. Empty the Bladder Before, During, or After Surgery.

e. Allows accurate measurement of urine output.

URINARY CATHETER SIZES

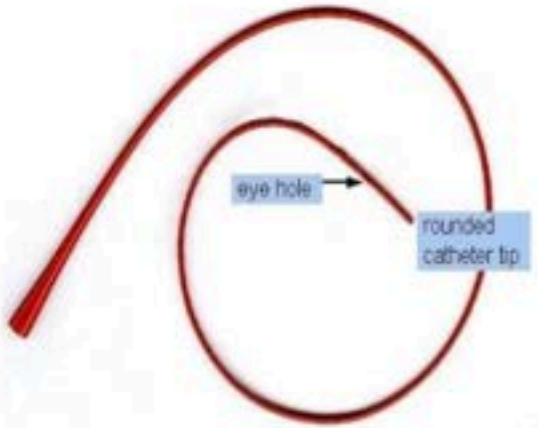
- The French scale (Fr.) is used to denote the size of catheters. Each unit is roughly equivalent to 0.33 mm in diameter (that is, 18 Fr. indicates a diameter of 6 mm). The smaller the number, the smaller the catheter. A larger sized catheter is used for a male because it is stiffer, thus easier to push the distance of the male urethra.

  Catheters come in several sizes:

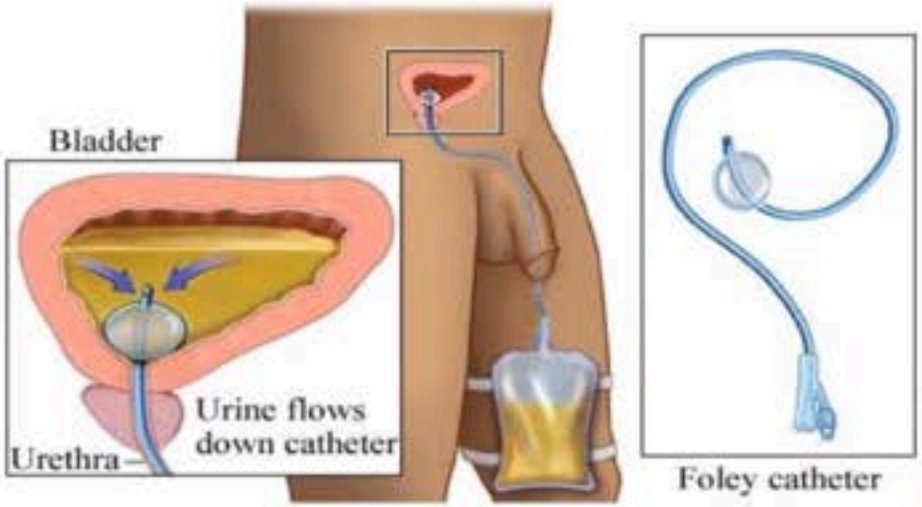
  - a. Number 8 Fr. and 10 Fr. are used for children.
  - b. Number 14 Fr. and 16 Fr. are used for female adults.
  - c. Number 20 Fr. and 22 Fr. are usually used for male adults.

TYPES OF URINARY CATHETERS

a. Intermittent Catheter. An intermittent catheter is used to drain the bladder for short periods (5-10 minutes). It may be inserted by the patient.

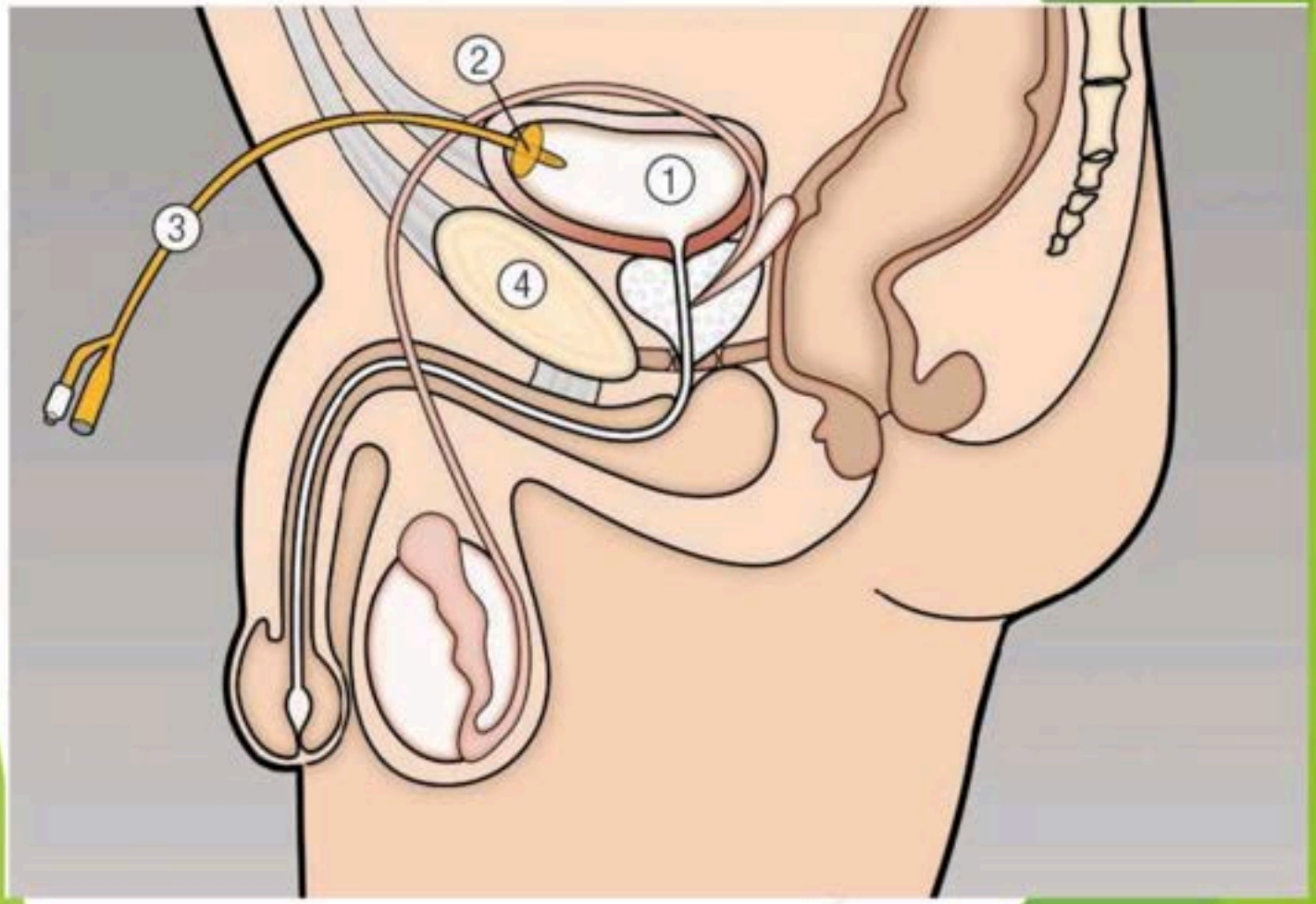


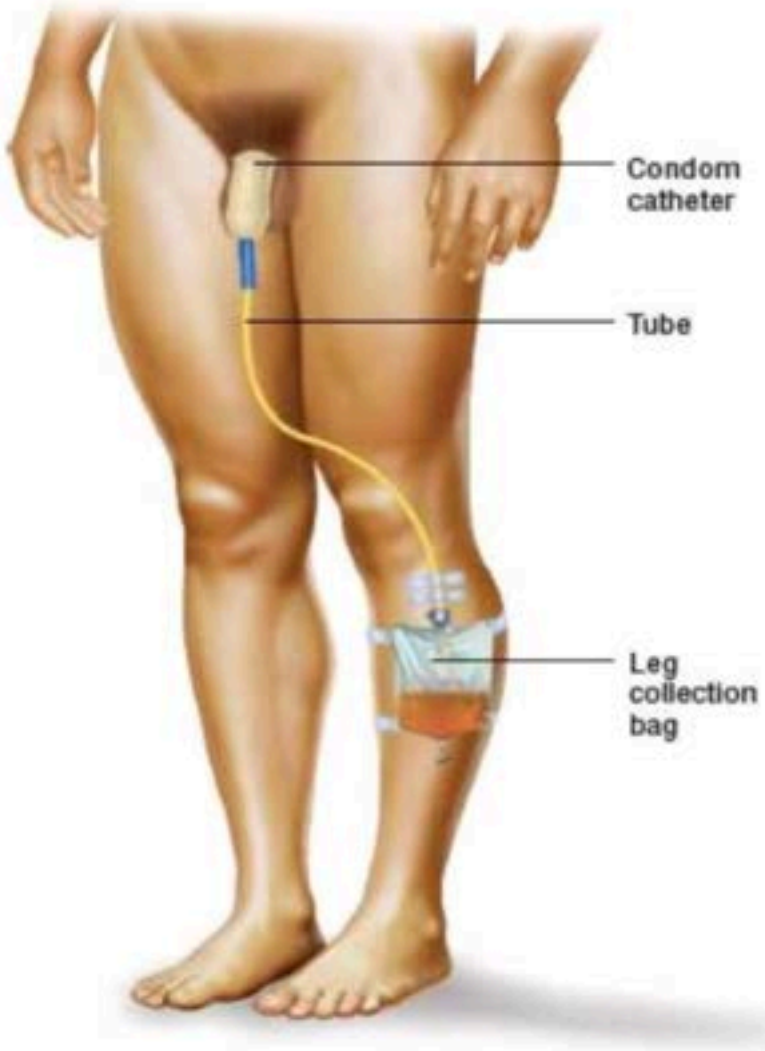
b. Retention/Indwelling Catheter. This type of catheter is placed into the bladder and secured there for a period of time.



c. Supra Pubic Catheter. This type of catheter is inserted into the bladder through a small incision above the pubic area. It is used for continuous drainage.

- Condom catheter
- Silicon catheter


2
1
3
4


Condom catheter
Tube
Leg collection bag

PREPARING FOR CATHETERIZATION

- A catheter should be used only when absolutely necessary and the catheterization procedure itself should be done only by trained personnel under sterile conditions. Infection is a major risk of urinary catheterization.

a. Gather All Equipment.

- Catheter
- 10cc syringe
- Sterile water
- Cotton balls with betadine
- Lubricant
- Sterile gloves.
- Flashlight or lamp.
- Urine collection bag.
- Velcro leg strap or anchoring tape.
- Disposal bag.

b. Explain the Procedure to the Patient.

c. Provide for Privacy and Adequate Lighting.

d. Positioning

- Position the female patient in a dorsal recumbent position with the knees flexed and the feet about two feet apart. Cover the upper body and each leg. Place the catheter set between the female patient's legs.
- Position a male patient in a supine position. Drape the patient so that only the area around the penis is exposed. Place the catheter set next to the legs of the male patient.

INSERTING THE FOLEY CATHETER IN A MALE PATIENT

a. Cleanse the genital and perineal areas with warm soap and water. Rinse and dry.

b. Wash your hands carefully.

c. Open the sterile catheterization kit, using sterile technique.

d. Put on the sterile gloves.

e. Open the sterile drape and place on the patient's thighs. Place fenestrated drape with opening on the penis.

f. Apply sterile lubricant liberally to the catheter tip. Lubricate at least six inches of the catheter. Leave the lubricated catheter on the sterile field.

g. Pour the antiseptic solution over the cotton balls.

h. Place the urine specimen collection container within easy reach.

i. Grasp the patient's penis between your thumb and forefinger of your nondominant hand. Retract the foreskin of an uncircumcised male. The gloved hand that has touched the patient is now contaminated.

j. Use the forceps to hold the cotton balls.This will maintain the sterility of one hand. Using the forceps, pick up one cotton ball and swab the center of the meatus outward in a circular manner.

k. Continue outward, using a new cotton ball for each progressively larger circle. Clean the entire glands. Deposit each cotton ball in the disposal bag. After the last cotton ball is used, drop the forceps into the disposal bag as well.

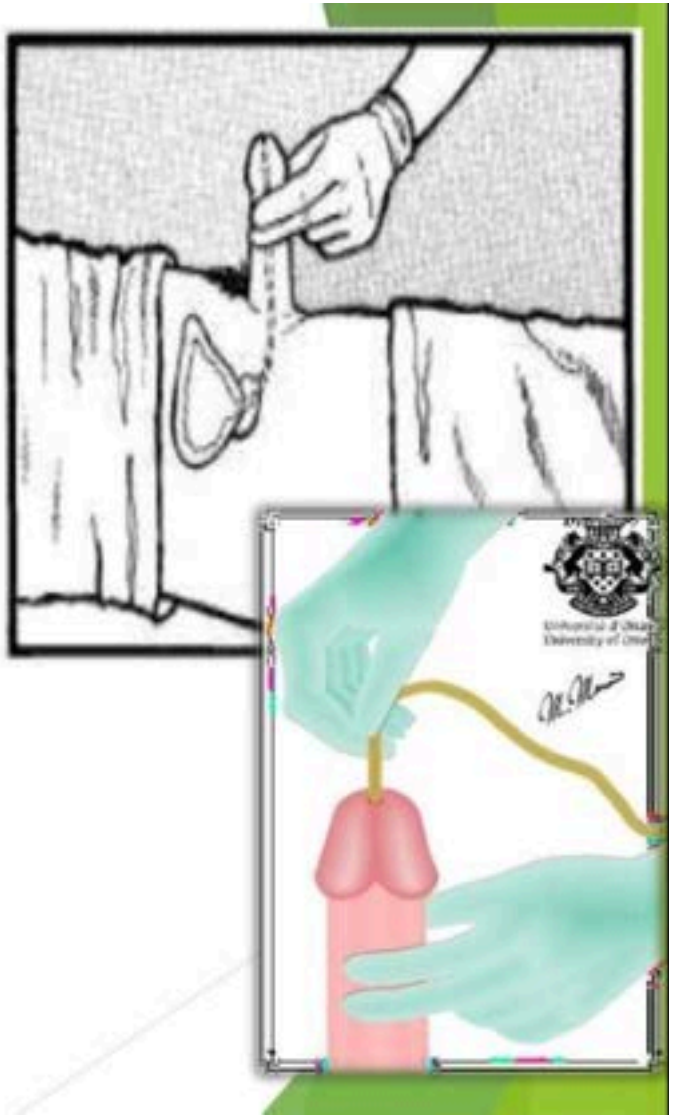


l. Hold the penis at a 90-degree angle. Advance the catheter into the patient's urinary meatus. You may encounter resistance at the prostatic sphincter.

(1)Pause and allow the sphincter to relax.

(2)Lower the penis and continue to advance the catheter.

NOTE: Never force the catheter to advance. Discontinue the procedure if the catheter will not advance or the patient has unusual discomfort. Get assistance from the charge nurse or physician.

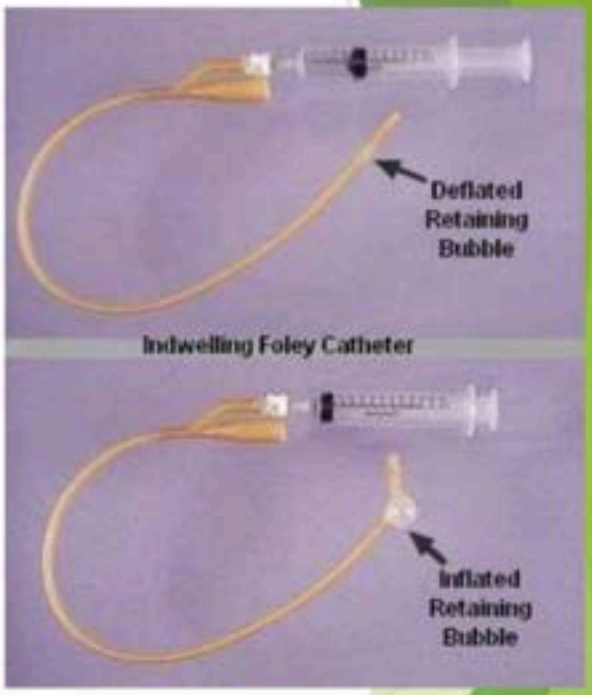


m. When the catheter has passed through the prostatic sphincter into the bladder, urine will start to flow. Gently insert until 1 to 2 inches beyond where urine is noted

n. Inflate balloon, using correct amount of sterile liquid (usually 10 cc but check actual balloon size)

o. Gently pull catheter until inflation balloon is snug against bladder neck

p. Connect catheter to drainage system



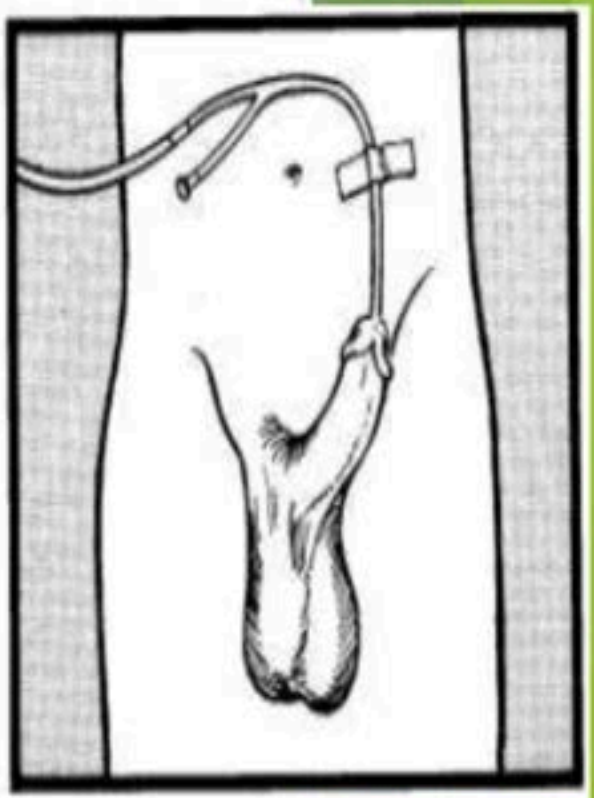
q. Anchor the catheter tubing to the lateral abdomen with tape, without tension on tubing

r. Place drainage bag below level of bladder

s. Evaluate catheter function and amount, color, odor, and quality of urine

t. Remove gloves, dispose of equipment appropriately, wash hands

u. Document size of catheter inserted, amount of water in balloon, patient's response to procedure, and assessment of urine



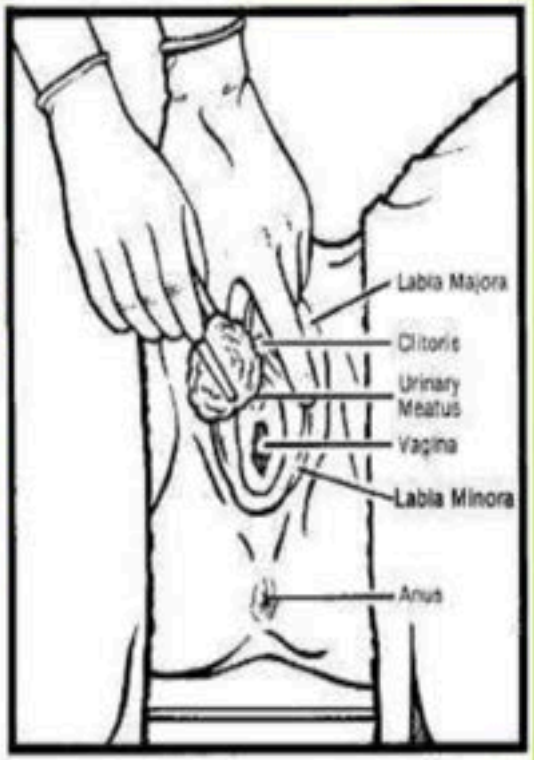
INSERTING THE FOLEY CATHETER IN A FEMALE PATIENT

- Follow procedure same with male from step a-h.

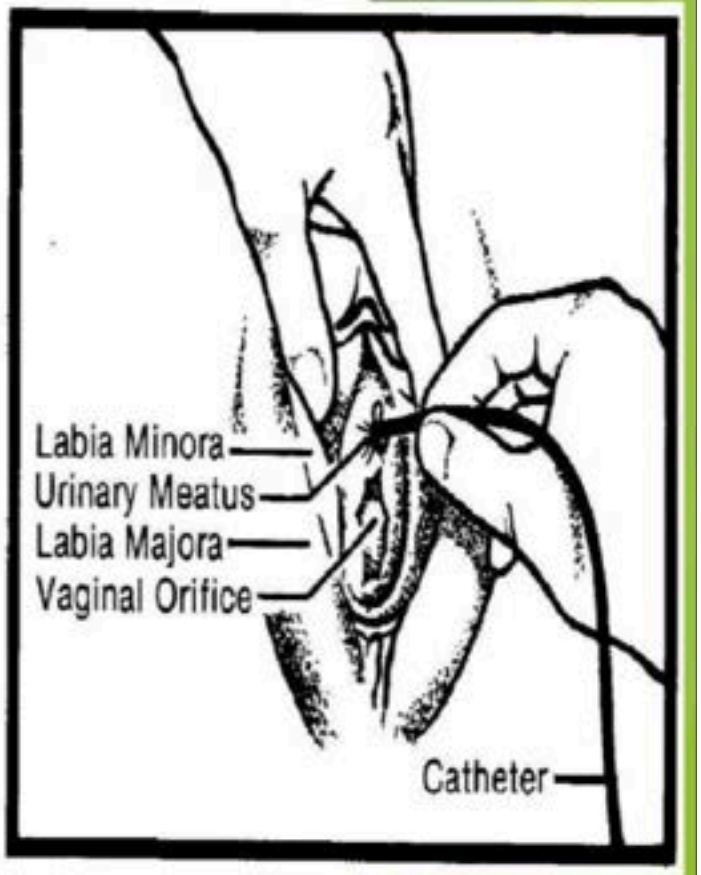




- Place the thumb and forefinger of your nondominant hand between the labia minora, spread and separate upward. The gloved hand that has touched the patient is now contaminated.
- Using the forceps, pick up a cotton ball saturated with antiseptic solution. Use one cotton ball for each stroke. Swab from above the meatus downward toward the rectum.
- Keeping the labia separated, cleanse each side of the meatus in the same downward manner Do not go back over any previously cleansed area.
- Deposit each cotton ball into the disposal bag. After the last cotton ball is
  - used, deposit the forceps into the bag as
  - well.

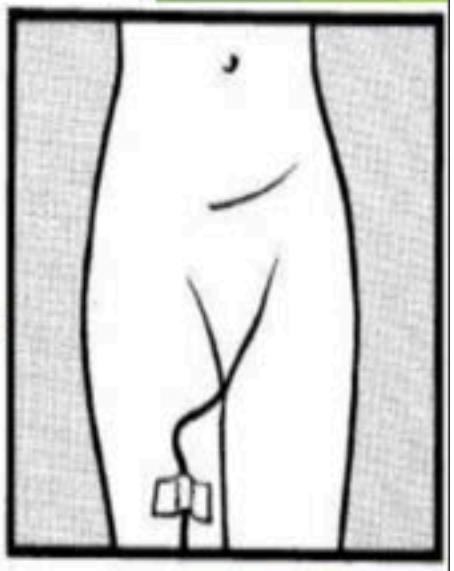


- Continue to hold the labium apart after cleansing. Insert the lubricated catheter into the female patient's urinary meatus.
- Angle the catheter upward as it is advanced. If the catheter will not advance, instruct the patient to inhale and exhale slowly. This may relax the sphincter muscle. Do not force the catheter.
- When urine starts to flow, insert the catheter approximately one inch further. Place the cup under the stream of flowing urine to obtain a sterile specimen if required.



- Inflate balloon, using correct amount of sterile liquid (usually 10 cc but check actual balloon size)
- Gently pull catheter until inflation balloon is snug against bladder neck
- Connect catheter to drainage system

- Connect the drainage bag to the catheter. Secure the catheter to the inner aspect of the female patient's thigh
- Place drainage bag below level of bladder
- Evaluate catheter function and
  - amount, color, odor, and quality of urine
- Remove gloves, dispose of equipment
  - appropriately, wash hands
- Document size of catheter inserted, amount of water in balloon, patient's response to procedure, and assessment of urine



REMOVING AN INDWELLING CATHETER

- Assemble all supplies and equipment.
  (1) 10 cc syringe.
  (2) Washcloth and towel.
  (3) Exam gloves.
  (4) Soap and water.
- Identify the patient and explain the procedure to him. Advise him that there will be a slight burning during removal of the catheter.
- Provide privacy and assist the female patient into a dorsal recumbent position. The male should be in a supine position.

- Wash your hands and put on exam gloves.
- Empty the balloon by inserting the barrel of the syringe and withdrawing the amount of fluid used during inflation.
- Pinch off and gently pull on the catheter near the point where it exits from the meatus.
- Clean the perineum or penis with soap and water. Dry the area well.
- Inspect the catheter to be sure no remnants remained in the bladder. If the catheter is not totally intact, report this promptly and save the catheter for further inspection.
- Empty the drainage bag. Measure the amount of urine and record on the intake and output (I&O) sheet.
- Remove the gloves and wash your hands.
- Discard disposable supplies and return reusable supplies and equipment to the appropriate area.

- Record that the catheter was removed, the time and date and by whom. Note the amount, color, and clarity of the urine in the drainage bag. Also document all patient teaching done and the patient's level of understanding.
- After removal of the catheter, assess the patient for 24 hours for patterns of urinary elimination. Note the time and amount of the first voided urine. Report any of the following:
  - Inability to void within 8 to 10 hours.
  - Frequency, burning, dribbling, or hesitation in starting the stream of urine.
  - Cloudiness or any other unusual color or characteristic of the urine.
  - Provide a level of fluids similar to the intake when the catheter was in place.
  - Record that the catheter was removed, the date and time, and by whom.

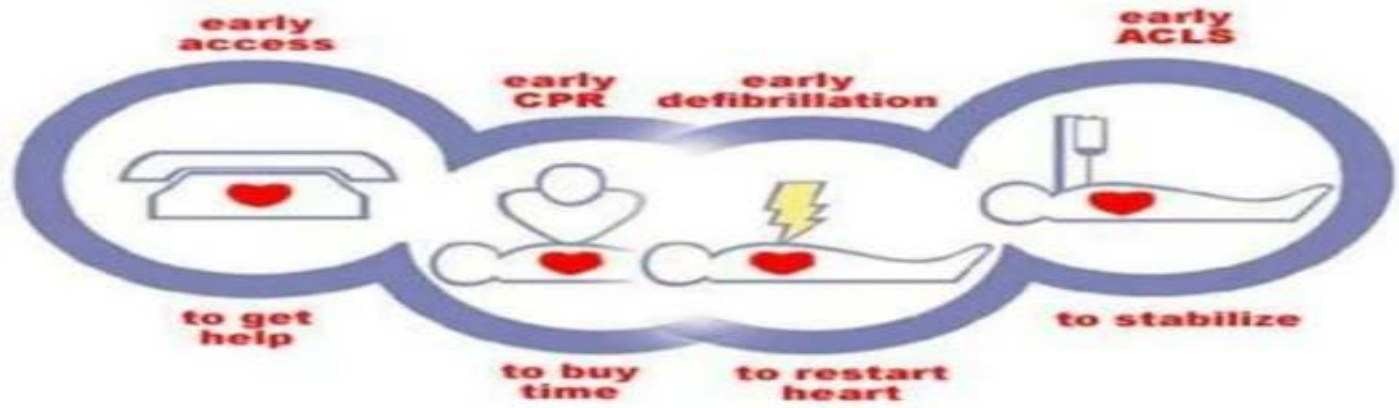
Thank you

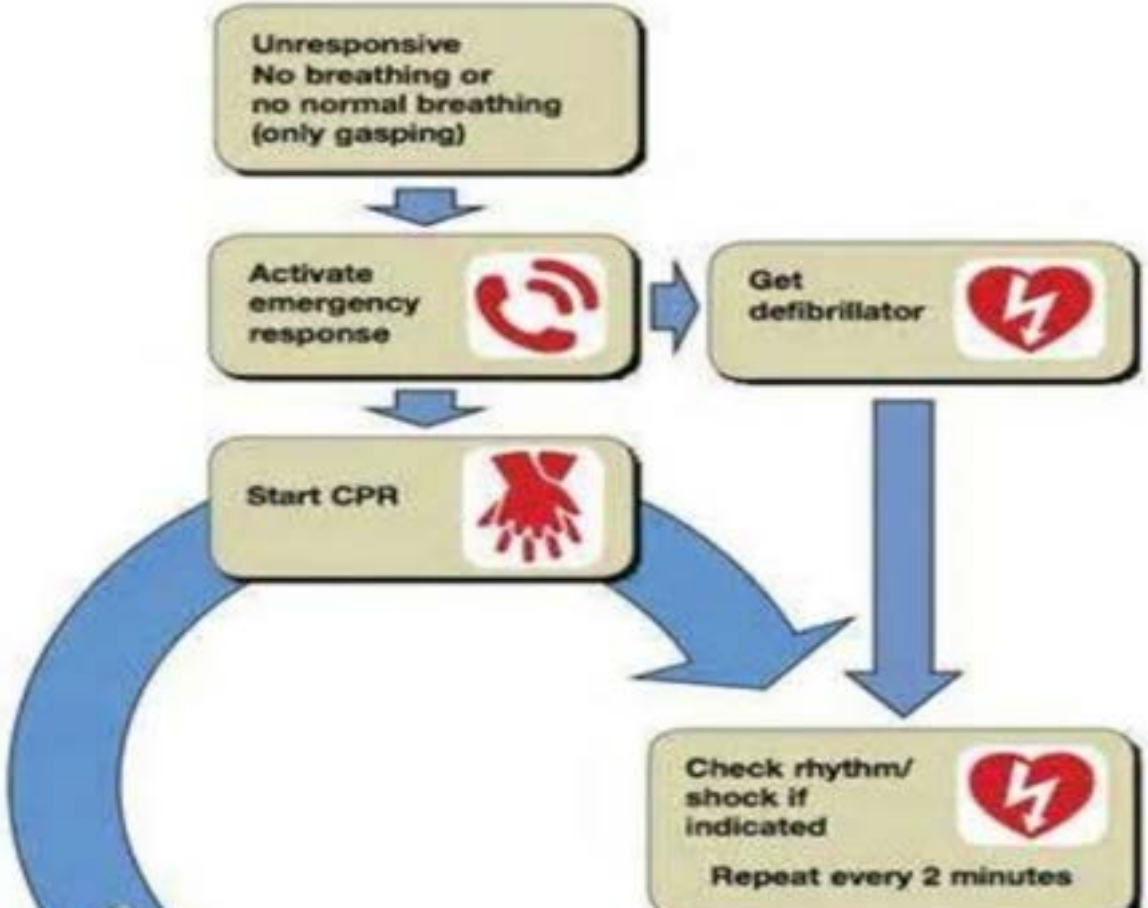


BASIC LIFE SUPPORT



CHAIN OF SURVIVAL




Unresponsive
No breathing or
no normal breathing
(only gasping)
Activate
emergency
response
Get
defibrillator
Start CPR
Check rhythm/
shock if
indicated
Repeat every 2 minutes

STEPS OF BLS



1.SCENE SAFETY

Look around to see if it is safe to approach





Tap the victim's shoulder and shout "Are you okay?"



Check to see if the victim is breathing by looking at their chest. If they are not breathing, or not breathing normally (only gasping)

2.ACTIVATE EMERGENCY MEDICAL SERVICES



If you are alone then shout for help and if no one responds CALL 102 & and ask to get an AED

3.PULSE CHECK

- Check the carotid pulse
- Locate the trachea using 2or 3 fingers.
- Slide fingers into groove between the trachea and muscles at side of neck
- Feel pulse for atleast 5 but no more than 10 secs.

No pulse start CPR



4.BEGIN CPR

- Position yourself at victim's side.
- Make sure victim is lying on flat surface with faceup
- Put heel on center of victim's chest on lower half of the breast bone.
- Put heel of one hand on top of first hand
- Straighten your arms and position shoulder directly over hands.



- Push HARD(at least 5cms/2 inches)
- Push FAST(at least 100 compressions per minute)
- Allow chest recoil to allow blood to flow into heart.
- Minimize interruptions



5.OPENING AIRWAY

Open the airway and give 2 breaths using a pocket mask or bag valve mask.



Fig. 1. The effect of the triple airwa manoeuvre aided by an oral pharyngeal airway.



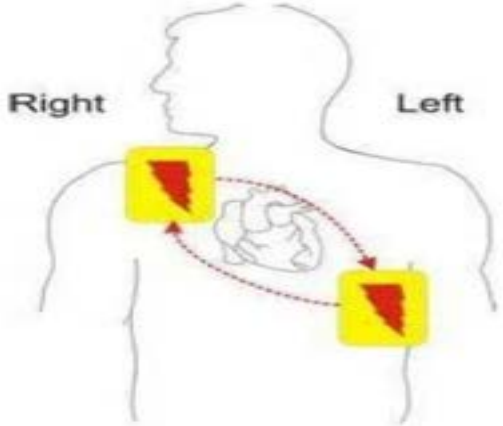


Continue 5 sets of 30 compressions and 2 breaths until the ambulance arrives to take over, the AED arrives, or you are too tired to continue



HOW TO USE AN AED

1. Power on the AED and follow the AEDs spoken directions
2. Attach the AED pads to the victim's bare chest



3. Say in a loud voice “clear”





4. If the AED advises a shock, clear the victim
5. Press the Shock button
6. Immediately resume CPR. After 5 cycles the AED will prompt you to repeat steps 3 and 4.


Thank You

OXYGEN THERAPY



Out line

- Definition of the oxygen therapy.
- Types of oxygen therapy.
- Purposes of using the oxygen therapy.
- Administration of oxygen therapy.
- Complication of oxygen therapy.

Learning objectives:

- Define the oxygen therapy.
- Discuss the type of oxygen therapy.
- List the purpose of using the oxygen therapy.
- Explain the procedure.
- Demonstrate the procedure.
- List Complication of oxygen therapy

Oxygen therapy Definition

- Oxygen is a colorless, odorless, tasteless gas that is essential for the body to function properly and to survive

What is meaning of O2 therapy

- Oxygen therapy is the administration of oxygen at a concentration of pressure greater than that found in the environmental atmosphere.
- The air that we breathe contain approximately 21% oxygen.
- The heart relies on oxygen to pump blood.

Purpose

- Oxygen therapy is a key treatment in respiratory care.
- The purpose is to increase oxygen saturation in tissues where the saturation levels are too low due to illness or injury.

Oxygen therapy is used to treat

- Example in case :
- Documented hypoxemia
- Severe respiratory distress (acute asthma or pneumonia)
- Severe trauma
- Chronic obstructive pulmonary disease (COPD, including chronic bronchitis, emphysema, and chronic asthma)

- Pulmonary hypertension
- Acute myocardial infarction (heart attack)
- Short-term therapy, such as postanesthesia recovery.
- Oxygen may also be used to treat chronic lung disease patients during exercise.

Preparation

- A physician's order is required for oxygen therapy, except in emergency use. Clinical observations.
- Indicated in Artial Blood Gas measurements,(ABGs) .

Pulse Oximetry.



Cautions For Oxygen Therapy

- Oxygen toxicity – can occur with FIO2 > 50% longer than 48 hrs
- Danger of fire
- Infection

Classification of Oxygen Delivery Systems

- **Low flow systems**
- contribute partially to inspired gas client breathes
- Ex: nasal cannula, simple mask , non-re breather mask , Partial rebreather mask
- **High flow systems**
- deliver specific and constant percent of oxygen independent of client's breathing
- Ex: Venturi mask,, trach collar, T-piece

Table 111-1. Oxygen Delivery Devices, Maximal Flow Rates, and Maximal Fraction of Inspired Oxygen Achievable				
Device	**Maximal Flow rate**	**Maximal FIO_2 Achievable**	**Flow**	**Entrainment of Room Air**
Nasal cannula	0.5–4 L/min	Variable	Variable	Yes
Simple face mask	6–10 L/min	30%–60%	Variable	Yes
Partial rebreathing mask	10–12 L/min	50%–60%	Variable	Yes
Nonrebreathing mask	10–12 L/min	≤95%	Relatively fixed	No
Oxygen hood	10–15 L/min	80%–90%	Relatively fixed	No
Oxygen tent	10–15 L/min	30%–50%	Variable	Yes
Venturi mask	Variable	Variable, predictable	Fixed	Yes

Methods of oxygen administration
Nasal cannula



Nasal cannula

- It is a disposable.
- Plastic devise with two protruding prongs for insertion into the nostrils, connected to an oxygen source.
- Used for low-medium concentrations of Oxygen (24-44%).

- Method Nasal Cannula Amount Delivered F1o2 (Fraction Inspired (Oxygen Priority Nursing Advantages Disadvantages
- Client able to talk and eat with oxygen in place
- May cause irritation to the nasal and pharyngeal mucosa Interventions

NASAL CANNULA

- Easily used if oxygen in home flow rates are setting above 6 liters/minute Variable FIO2

Face masks

- The simple oxygen mask
- The partial rebreather mask
- The non rebreather mask
- The venturi mask

The Simple Oxygen Mask

- Simple mask is made of clear, flexible , plastic or rubber that can be molded to fit the face.



The simple Oxygen mask

- It delivers 35% to 60% oxygen.
- A flow rate of 6 to 10 liters per minute.
- Often it is used when an increased delivery of oxygen is needed for short periods (i.e., less than 12 hours).

The partial rebreather mask

- The mask is have with a reservoir bag must romaine inflated during both inspiration & expiration.
- It collection of the first parts of the patients' exhaled air.
- It is used to deliver oxygen concentrations up to 80%.

PARTIAL REBREATHING MASK



The partial rebreather mask

- The oxygen flow rate must be maintained at a minimum of 6 L/min to ensure that the patient does not rebreathe large amounts of exhaled air.
- The remaining exhaled air exits through vents.

The non rebreather mask

- This mask provides the highest concentration of oxygen (95-100%) at a flow rate6-15 L/min.
- It is similar to the partial rebreather mask except two one-way valves prevent conservation of exhaled air.
- The bag is an oxygen reservoir

NON REBREATHING MASK

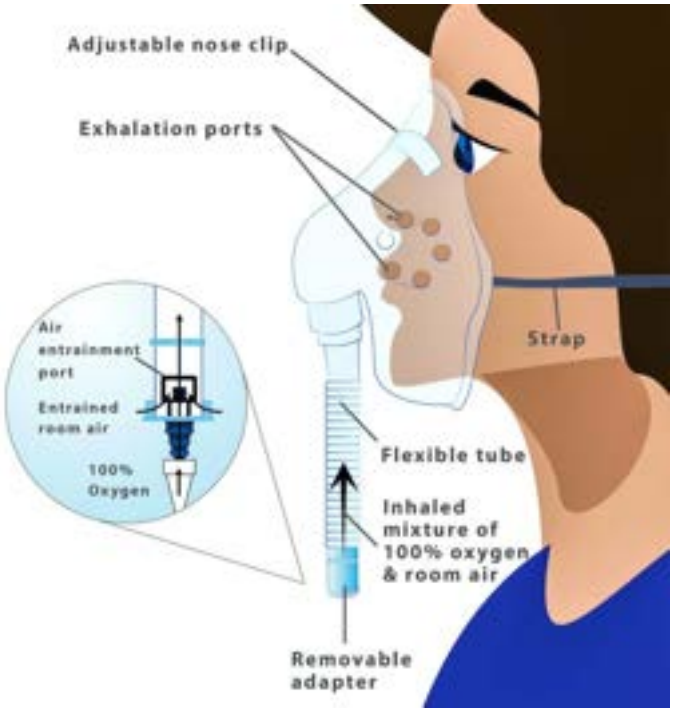


Venturi mask

- It is high flow concentration of oxygen.
- Oxygen from 40 – 50%
- At liters flow of 4 to 15 L/min.

Venturi Mask

- Designed to deliver a specific oxygen concentration to avoid over oxygenation.
- comes with a 7 ft tubing and are made of medical grade PVC.
- Transparent mask allows to monitor facial color & vital functions.
- Patient friendly with comfortable mask.
- There are multiple color coded diluters for easy oxygen rate identification that varies from 24-60%.
- Latex free.



T-piece

- Used on end of ET tube when weaning from ventilator.
- Provides accurate FIO2 Provides good humidity.



Side effect & complication of oxygen therapy

- Oxygen toxicity
- Retrolental fibroplasia
- Absorption atelectasis

Oxygen toxicity

- It is a condition in which ventilator failure occurs due to inspiration of a high concentration of oxygen for aprolonged period of time.
- Oxygen concentration greater than 50% over 24 to 48 hours can cause pathological changes in the lungs.

Signs and symptoms of oxygen toxicity

- Non-productive cough
- Nausea and vomiting
- Substernal chest pain
- Fatigue
- Nasal stuffiness
- Headache
- Sore throat
- Hypoventilation
- Nasal congestion.
- Dyspnea.
- Inspiration pain .

Evaluation

- Breathing pattern regular and at normal rate.
- Pink color in nail beds, lips, conjunctiva of eyes.
- No confusion, disorientation, difficulty with cognition.
- Arterial oxygen concentration or hemoglobin.
- Oxygen saturation within normal limits.

Documentation

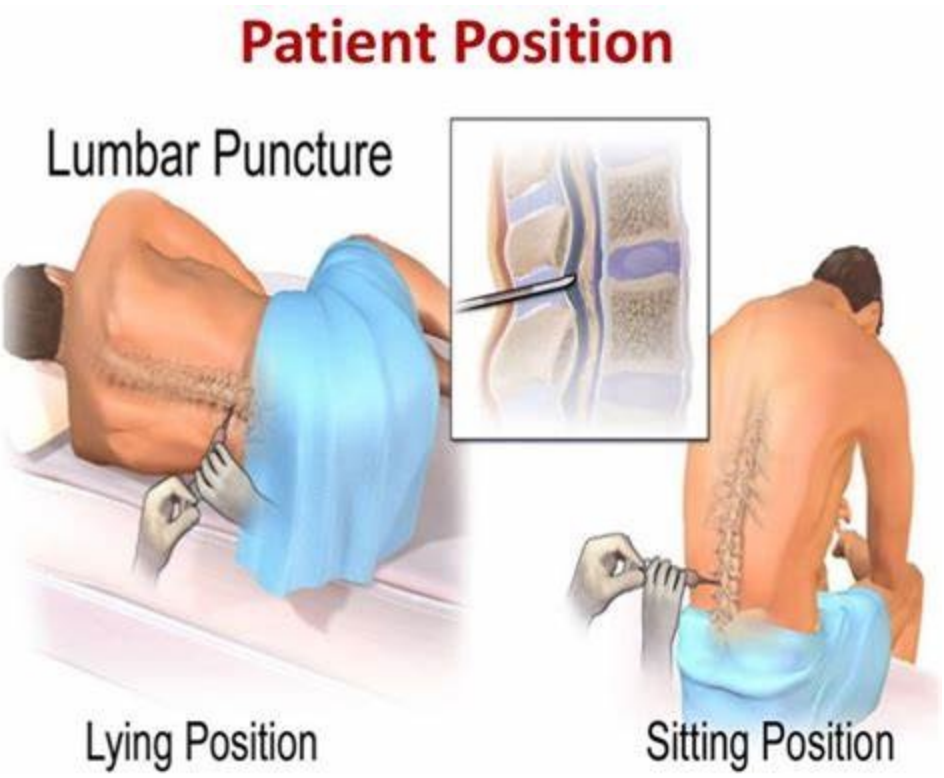
- Date and time oxygen started.
- Method of delivery.
- Oxygen concentration and flow rate.
- Patient observation.
- Add oronasal care to the nursing care plan

THANK YOU

LUMBAR PUNCTURE

DEPARTMENT OF MEDICINE
DUPMC

Lumber punctur
cerebrospinal f
the spinal sub-a
by puncturir
between lum
lumbar 3 and



LUMBAR PUNCTURE

INDICATION

- DIAGNOSTIC
- A. Absolute: 1. Meningitis
  2. Subarachnoid hemorrhage

- B. Relative: 1. Neurosyphilis
  2. Unexplained coma
  3. Guillain Barre syndrome
  4. Multiple sclerosis

- C. Radiological: 1. Myelography
  2. Pneumoencephalography (P.E.G.)

INDICATIONS

- **II. Therapeutic**
- A. To introduce drugs: 1. Methotrexate 0.25 mg/kg biweekly in leukemia
- 2. Gentamicin 10-20 mg in gram negative meningitis
- 3. Crystalline Penicillin 10,000-20,000 units in pyogenic meningitis

- B. To reduce raised intro-cranial tension in hypertensive encephalopathy

- C. To administer spinal anesthesia

CONTRADICTION

- 1. Raised intracranial tension because of the risk of herniation of brain through foramen magnum, and damaging the vital medullary centres causing death.
- 2. Marked spinal deformity
- 3. Local infections
- 4. Suspected cord compression

PROCEDURE

- 1. Position: The patient is placed on his side at the edge of the bed with the knee drawn up and the head flexed. It can also be done with the patient sitting and bending forward.
- 2. Site: In the 3rd lumbar space. This space lies in the plane which joins the highest points on the iliac crest. The skin over the back from the lower thoracic vertebrae to the coccyx is sterilized with Cetavlon, ether, iodine and spirit. The part is draped.
- 3. Local anesthesia: The skin to be punctured is infiltrated with 5 ml of2% lignocaine. Infiltration is done up to ligamentum flava
- 4. Puncture: A lumbar puncture needle with a stilette is introduced after 2-3 minutes into the anesthetized space, with the cutting edge of the bevel in the direction parallel to the fibers of the ligamentum flava. The needle is introduced (slightly upwards and forwards at 5 ° to avoid injury to the disc) through the resistance of supraspinous ligament. The interspinous ligament is then easily negotiated. At about 4-7 cm, the firmer resistance ofligamentum flavum popping sensation as the dura is breached. The stilette is then withdrawn and the fluid is collected slowly in 4-5 bulbs for biochemical, cytological and serological tests.
- Seal: The needle is withdrawn and the puncture mark is sealed with a tincture benzoin seal
- Post-procedure orders: a. Plenty of fluids are to be taken by mouth. b. Head low position, with half to one block to prevent headache c. Salicylates, if headache

PROBLEMS

- **I. Dry Tap**
- A. The needle is blocked: Re-insert the stilette to dislodge any flap of dura that may have blocked the needle.
- B. Faulty technique: Repeat the procedure.
- C. Subarachnoid block
- **II. Bloodstained CSF**
- A. Trauma to the spinal blood vessels.
- B. Subarachnoid hemorrhage. To distinguish between these conditions. CSF must be collected in 2 parts is separate test tubes. The appearance of more blood in one sample compared to the other suggests trauma; in subarachnoid hemorrhage it is uniform

COMPLICATIONS

- 1. Headache is the commonest problem. To minimise this, plenty of fluids should be taken orally, head-low position is to be given and salicylates if required. In neurosyphilis, headache never occurs following lumbar puncture
- 2. Backache
- 3. Infection: Often causing gram-negative meningitis
- 4.Medullary herniation leading to death
- 5. Injury to the blood vessels, spinal cord or intervertebral disc
- 6. Aggravation of symptoms from which the patient is suffering eg root pains, paraplegia, etc.

RYLE TUBE INSERTION

RYLES TUBE



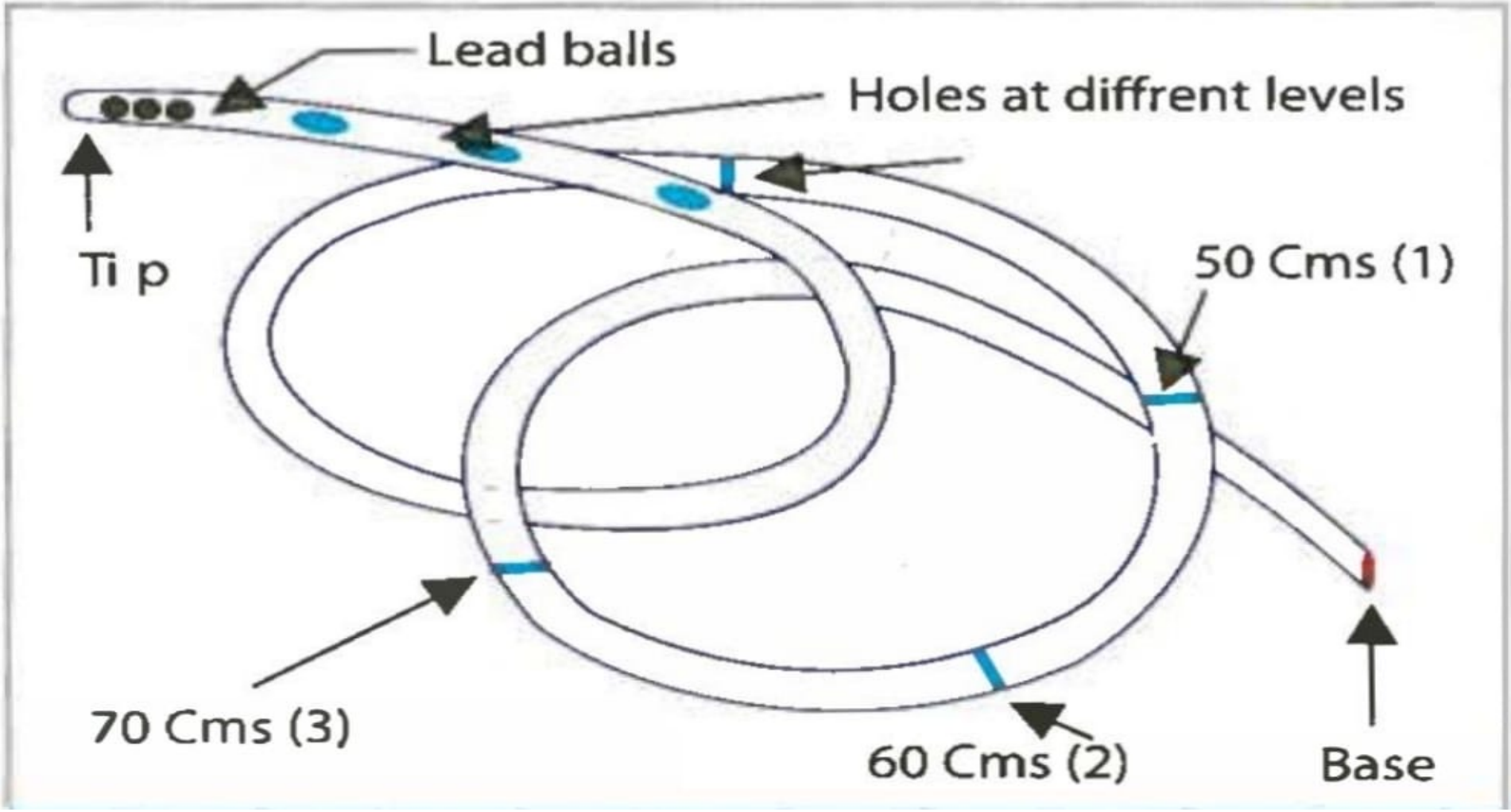
Types of tubes

-**Short tubes**: passed through nose into stomach -**Medium tubes**: through nose to duodenum & jejunum

-**Long tubes**: through nose ,esophagus,stomach into the intestine

-**SIZE**:10F to 20F LENGTH:105-120 cm

COMPONENT OF RYLES TUBES



RYLES TUBE

STERILIZATION:

- Gamma rays irradiation at the bhabha atomic research
- Ethylene oxide gas sterilization
- Boiling

USES OF RYLES TUBE

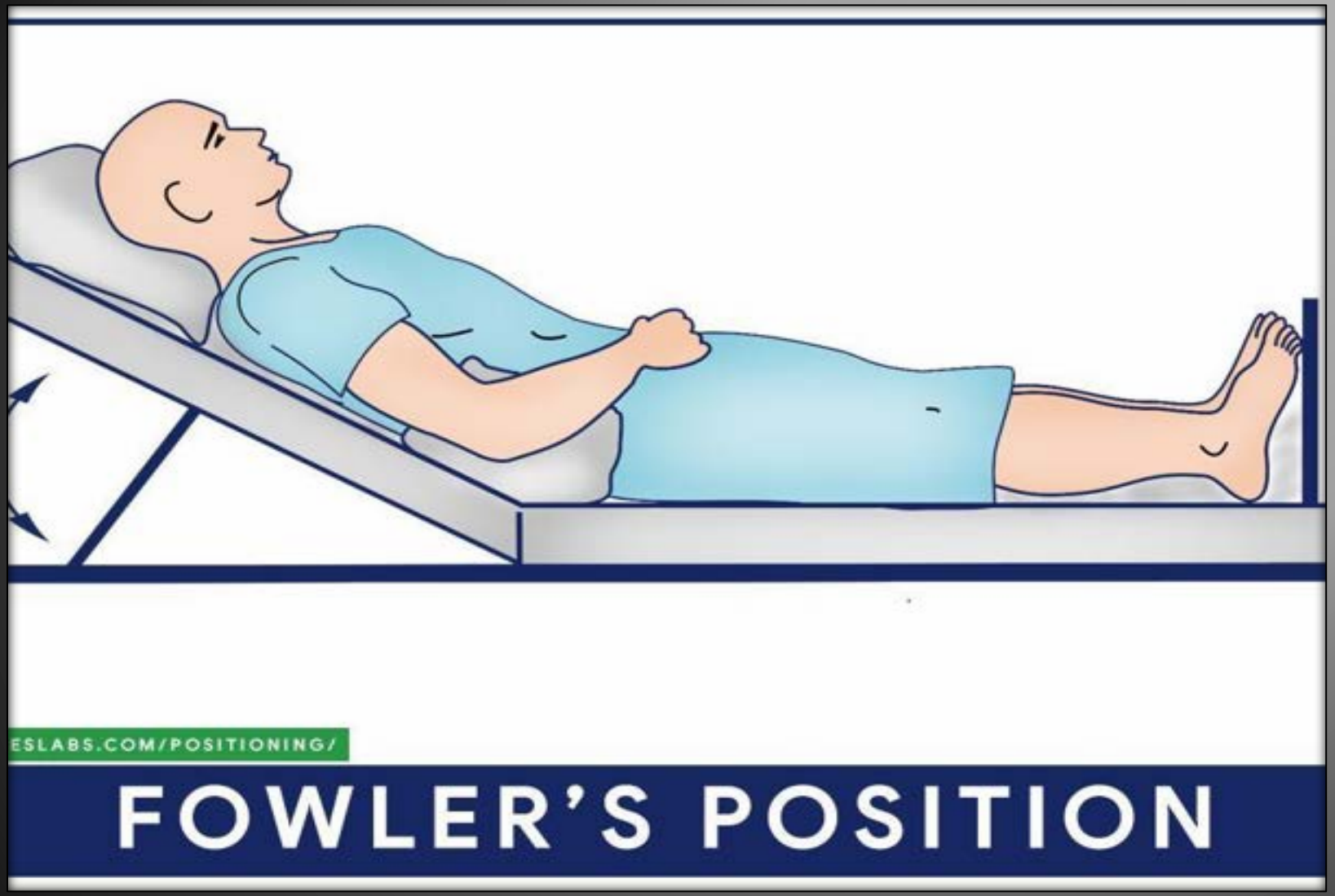
- **DIAGNOSTIC –**
- Upper gastro-intestinal bleeding: In cases of hematemesis or malena, the RT is inserted and gastric fluid is aspirated to diagnose upper GI bleeding.
- Gastric Analysis: To diagnose peptic ulcer disease, Zollinger Ellison syndrome, achlorhydria, etc.
- Poisoning: Aspirate sent for analysis
- Exfoliative cytology: For diagnosis of stomach cancer
- Tuberculosis in children: Acid Fast Bacilli (AFB) in the aspirate in children who cannot produce sputum or swallow it. Early morning aspiration is preferred.
- Tracheo-esophageal fistula: In newborns, there will be an obstruction to the passage of the RT or the RT will coil up in the blind esophagus.

USES OF RYLES TUBE

- **Therapeutic**
- Enteral feeding of nutrients or drugs for patients who cannot ingest it orally
- Gastric lavage or stomach washes in case of poisoning and hematemesis.
- Gastric decompression in intestinal obstruction, paralytic ileus, acute gastric dilation, peritonitis or post operatively.
- In acute cholecystitis or acute pancreatitis: to give rest to the bowel

PROCEDURE

- Determine the length of tube to be inserted- Measure distance from tip of nose to earlobe & to xyphoid process of sternum.
- Tube:lubricated with sterile paraffin or jelly
- Nose:wider nostril selected Nostril cleaned with pledgent of cotton wool Moistened with savlon in water
- Patient in sitting position /fowler's position. When patient is lying ,head should be flexed by one hand .Tip-passed along nasal septum & horizontally along floor of nose


ESLABS.COM/POSITIONING/
FOWLER'S POSITION

CONTRAINDICATIONS

- Corrosive poisoning
- Kerosene poisoning

PRECAUTIONS

- RT Feeding: The patient has to be propped up. There should be 2 hours between feeds. Before feeding, aspirate the gastric content to check if at least one third the contents have been emptied or not. If not, the feed should be delayed. The RT should be flushed after the feeding. The patient should be propped up for at least half an hour after the feed.

COMPLICATIONS

- 1. Epistaxis, rhinitis
- 2. Pharyngitis
- 3. Esophagi tis, esophageal perforation, rupture and bleeding of esophageal varices
- 4. Reflux esophagitis since lower esophageal sphincter is incompetent
- 5. Gastritis,gastric bleeding (ifover-zealous suction done rapidly)
- 6. Aspiration pneumonia if tracheal insertion not detected
- 7. Hypokalemic, hypochloremic, metabolic acidosis if overzealous suction

PLEURAL TAPPING

INTRODUCTION

- Thoracentesis is a procedure in which a needle is inserted into the pleural space between the lungs and the chest wall. This procedure is done to remove excess fluid, known as a pleural effusion, from the pleural space to help you breathe easier.

DEFINITION

- Thoracentesis is a procedure to remove fluid from the space between the lungs and the chest wall called the pleural space. OR • Thoracentesis is a procedure that removes an abnormal accumulation of fluid or air from the chest through a needle or tube.

PURPOSE

- To determine the cause of abnormal accumulation of fluid in the pleural space. • Relieve shortness of breath and pain • As a diagnostic or treatment procedure • To drain large amounts of pleural fluid • To equalize pressure on both sides of the thoracic cavity

INDICATION AND CONTRAINDICATION

- INDICATION
- Traumatic pneumothorax • Hemopneumothorax • Spontaneous pneumothorax • Bronchopleural fistula • Pleural effusion

- CONTRAINDICATION

• An uncooperative patient • Coagulation disorder • Atelectasis • Only one functioning lung • Emphysema (pulmonary enlargement) • Severe cough or hiccups

COMPLICATIONS

- Pulmonary edema • Respiratory distress • Air embolism • Cardiac tamponade (fluid build up in the space between myocardium and pericardium) • Bleeding • Infection • Dyspnea and cough • Atelectasis

EQUIPMENT

- Dressing set
- Abraham’s needle
- Connecting tubing
- Syringe 50ml and 5ml
- Scalpel blade and blade 11
- Needles (18 and 23 gauge)
- Sterile Glove
- Mask
- Povidone / Alcohol
- Local anaesthetic, e.g. lignocaine (lidocaine) 1% or 2% Formalin bottle
- Urine bottle x2
- C+S bottle
- 3-way

BEFORE THE PROCEDURE

- Check platelet count and/or presence of coagulopathy. If platelet count is < 20,000, or there is known coagulopathy as to whether platelet transfusion or other intervention is needed.
- Place patient upright / cardiac position and help patient maintain position during procedure. R: the upright position ensures that the diaphragm is more dependent and facilitates the removal of fluid that usually localizes at the base of the chest.
- Explain that he/she will receive a local anesthetic Clean patient skin with antiseptic soap
- Observe patient respiration rate and breathing pattern.

DURING THE PROCEDURE

- Monitor saturation R: To prevent hypoxia
- Inform doctor if any changes of the patient Obtain a chest x-ray to evaluate the fluid level.
- For specimen handling, fill the tubes with the required amount of pleural fluid
- Check that each bottle is correctly labelled by checking patient identifiers- full name, date of birth and/or medical record number then send to the lab tests

AFTER THE PROCEDURE

- Document the procedure, patient's response, characteristics of fluid and amount, and patient response to follow-up.
- Provide post-procedural analgesics as needed.
- Rest in bed for about 2 hours after the procedure
- Blood pressure and breathing will be checked for up to a few hours
- May remove dressing/bandage another day, or replace it if it becomes soiled or wet
- Resume patient regular diet.

23	2020-21	PATHOLOGY	KAMBLE PRIYANKA SHASHIKANT
24	2020-21	PSYCHITRY	SHAIKH MUJAHID KHADARSAB
25	2020-21	PSYCHITRY	YADAV GOVIND UDHAVRAO
26	2020-21	RADIO-DIAGNOSIS	BHARAPURIA KANISHKA RAVI
27	2020-21	RADIO-DIAGNOSIS	BHOSALE ABHIJEET DNYANESHWAR
28	2020-21	RADIO-DIAGNOSIS	SHEIKH MOHAMMAD ZAINUL
29	2020-21	SKIN	KALBANDE PRAJAKTA PRAKASH
30	2020-21	SKIN	SHAIKH MUBINA IRFAN
31	2020-21	GENERAL SURGERY	ANISH AVINASH JOSHI
32	2020-21	GENERAL SURGERY	FARKE VAIBHAV BALASAHEB
33	2020-21	GENERAL SURGERY	MANKAR SHUBHAM SHRIKRUSHNA
34	2020-21	GENERAL SURGERY	SHRIYASH KONDIBA SONAWANE
35	2020-21	GENERAL SURGERY	SIRPURAM VARUNDEV ASHOK
36	2020-21	TB,CHEST	LANGADE SUSHIL SURESH
37	2020-21	TB,CHEST	SAMADHAN DATTATRAYA BAHEKAR

I hereby certify that evaluation report of these candidates sign by BORS committee will be retained by the college till students is awarded P.G degree by the university.

You are requested to accept this letter and issue approval for Title & Synopsis of P.G candidates

Thanking you,

Dr. Ulhas Patil Medical College & Hospital ★ JALGAON KH

Dean

Dean
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospital
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-01/12/2020

Circular

Sub:- Formation of BORS Committee at our college.

Following members are requested to accept the membership of Board of Research Studies and perform necessary activities for thesis, title & Synopsis of P.G. students admitted in our college every year.

1) Dr. N. S. Arvikar - Chairman
2) Dr. Devendra Chaudhari – Prof. Pharmacology
3) Dr. Sadulwad Shivaji – Prof. Surgery
4) Dr. Kante C. A. – Prof. Medicine
5) Dr. Arvikar Maya N. – Prof. OBGY

Please Convey your acceptance.

Dean,
Dr. Ulhas Patil Medical College &
Hsopital, Jalgaon kh

Dean
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Dr. Ulhas Patil Medical College & Hospital ★ JALGAON KH

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

BOARD OF RESEARCH STUDIES

BORS/ 2022/ Minutes of Meeting

DATE: 10/10/2022
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1. Meeting attended by

Sr. No.	Member Name	Designation	Signature
1.	**Dr. N.S.Arvikar**	Chairman	
2.	**Dr. Devendra R. Chaudhari**	Member	
3.	**Dr. Mrs. Maya N. Arvikar**	Member	
4.	**Dr. Chandrayya Kante**	Member	
5.	**Dr. Shivaji Sadulwad**	Member	
6.	**Dr. Dilip Dhekale**	Member	
7.	**Dr.Neha Mahajan**	Member	
8.	**Dr.Vikrant Vaze**	Member	

2. Meeting Location

Dean's Office, Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh).

3. Meeting Start TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4. Meeting Agenda

a) To add the new members in committee.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date:-08/10/2022

CIRCULAR

All members of Board of Research Studies committee are informed that meeting is arranged in Dean's office on 10/10/2022 at 3.00 pm

All members are requested to attend meeting

Dr. Arvikar N. S.
Dean
Dr. Ulhas Pati Medical College
& Hospital, Jalgaon kh

Copy to all members

Dr. N.S.Arvikar
Dr. Devendra R. Chaudhari
Dr. Mrs. Maya N. Arvikar
Dr. Chandrayya Kante
Dr. Shivaji Sadulwad
Dr. Dilip Dhekale
Dr.Neha Mahajan
Dr.Vikrant Vaze

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

BOARD OF RESEARCH STUDIES

BORS/ 2022/ Minutes of Meeting

DATE: 07/11/2022
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1. Meeting attended by

Sr. No.	Member Name	Designation	Signature
1.	**Dr. N.S.Arvikar**	Chairman	
2.	**Dr. Devendra R. Chaudhari**	Member	
3.	**Dr. Mrs. Maya N. Arvikar**	Member	
4.	**Dr. Chandrayya Kante**	Member	
5.	**Dr. Shivaji Sadulwad**	Member	
6.	**Dr. Dilip Dhekale**	Member	
7.	**Dr.Neha Mahajan**	Member	
8.	**Dr.Vikrant Vaze**	Member	

2. Meeting Location

Dean's Office, Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh).

3. Meeting Start TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4. Meeting Agenda

a) To review and approve synopsis title of all PG students.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Date:-04/11/2022

CIRCULAR

All members of Board of Research Studies committee are informed that meeting is arranged in Dean's office on 07/11/2022 at 3.00 pm

All members are requested to attend meeting

Dr. Arvikar N. S.
Dean
Dr. Ulhas Pati Medical College
& Hospital, Jalgaon kh

Copy to all members

Dr. N.S.Arvikar
Dr. Devendra R. Chaudhari
Dr. Mrs. Maya N. Arvikar
Dr. Chandrayya Kante
Dr. Shivaji Sadulwad
Dr. Dilip Dhekale
Dr.Neha Mahajan
Dr.Vikrant Vaze

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

BOARD OF RESEARCH STUDIES

BORS/ 2020/ Minutes of Meeting

DATE: 04/12/2020
Location:
Dean's Office
Recorded By: Dr. Chaudhari

1. Meeting attended by

Sr. No.	Member Name	Designation	Signature
1.	**Dr. N.S.Arvikar**	Chairman	
2.	**Dr. Devendra R. Chaudhari**	Member	
3.	**Dr. Shivaji Sadulwad**	Member	
4.	**Dr. Chandrayya Kante**	Member	
5.	**Dr. Mrs) Maya N. Arvikar**	Member	

2. Meeting Location

Dean's Office, Dr. Ulhas Patil Medical College and Hospital Jalgaon (Kh).

3. Meeting Start TIME

Meeting Schedule Start: 03.30 pm

Meeting Actual Start: 03.35 pm

4. Meeting Agenda

a) To form the committee of Board of Research Studies.
b) To deliver appointment letter to members.
c) To introduce them the need and role of BORS Committee.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospita
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi,
and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax :2366648 E-Mail Id : dupmcj@yahoo.in

Date:-01/12/2020

Circular

Sub:- Formation of BORS Committee at our college.

Following members are requested to accept the membership of Board of Research Studies and perform necessary activities for thesis, title & Synopsis of P.G. students admitted in our college every year.

1) Dr. N. S. Arvikar - Chairman
2) Dr. Devendra Chaudhari – Prof. Pharmacology
3) Dr. Sadulwad Shivaji – Prof. Surgery
4) Dr. Kante C. A. – Prof. Medicine
5) Dr. Arvikar Maya N. – Prof. OBGY

Please Convey your acceptance.

Dean,
Dr. Ulhas Patil Medical College &
Hsopital, Jalgaon kh

Dean
Dr. Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's
Dr. Ulhas Patil Medical College & Hospita
Recognised by Medical Council of India, Approved by Central Govt. of India, New Delhi, and Affiliated to Maharashtra University of Health Science, Nashik
N.H.6 (Jalgaon- Bhusawal Road), Jalgaon (Kh.) - 425 309 Tal & Dist - Jalgaon
Ph. No. (0257) 2366657 Fax : 2366648 E-Mail Id : dupmcj@yahoo.in

GF/DUPMC/PG-Title & Synopsis/2021/169

Date: 03/09/2021

ANNEXURE-'D'

To,
The Registrar
Maharashtra University of Health Sciences,
Nashik-422001.

Subject: Information of Title of Synopsis proposal 'Accepted' by BORS(A.Y 2020-21).

Respected sir,

With reference to above subject I want to submit your office that title of synopsis of following students admitted in our college for academic year 2020-21 were placed before BORS for consideration.

After deliberation BORS has accepted title and synopsis of following students.

Sr. No.	Academic year	Subject	Name of the Candidate
1	2020-21	ANAESTHESIA	DESHPANDE HARSHA SANJAY
2	2020-21	ANAESTHESIA	KELGAONKAR VIJAYA VIVEK
3	2020-21	ANAESTHESIA	PRAJAKTA PRAKASH SHILAHAR
4	2020-21	ANAESTHESIA	SONONE SHIVAJI DILIP
5	2020-21	ENT	HARSHAL VASUDEO MAHAJAN
6	2020-21	ENT	KHANDAGALE SHRUTI SHAILENDRA
7	2020-21	GENERAL MEDICINE	KAMELI MOHAMMAD JUNAID RAFEEQUE AHMAD
8	2020-21	GENERAL MEDICINE	KOTECHA TEJAS KUNDAN
9	2020-21	GENERAL MEDICINE	NANDEDKAR ADITYA MAHADEV
10	2020-21	GENERAL MEDICINE	PRIYANKA ASHOK BHALKE
11	2020-21	GENERAL MEDICINE	WAGAJ SUSHANT PRAKASH
12	2020-21	OBGY	- DONGARWAR AKASHKUMAR SHALIKRAM
13	2020-21	OBGY	MAHESH GAJANAN DESHMUKH
14	2020-21	OBGY	YASHASHREE PRADIP DESHMUKH
15	2020-21	OPTHALMOLOGY	AKASH UTTAMRAO MALVI
16	2020-21	OPTHALMOLOGY	ANUJA VINAYAK GADGIL
17	2020-21	OPTHALMOLOGY	DESHMUKH KALPANA ARJUNRAO
18	2020-21	ORTHOPAEDICS	JANBANDHU RAHUL SHANTILAL
19	2020-21	ORTHOPAEDICS	PATIL PARIKSHIT PRATAP
20	2020-21	ORTHOPAEDICS	VELANKAR SUNEET NITIN
21	2020-21	PAEDIATRICS	RANGNEKAR PRADNIL KISHOR
22	2020-21	PAEDIATRICS	SHUKLA SURUCHI RAMPRASAD

Dr. Ulhas Patil Medical College & Hospital ★ JALGAON (KH.)

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Name of PG student	Department	Thesis Title
DR. NEHA P. RAGHUWANSHI	PATHOLOGY	CYTOMORPHOLOGICAL STUDY OF BREAST LESIONS IN WOMEN IN RELATION TO AGE, SIZE, LOCATION AND HISTOLOGICAL FINDINGS"
Dr. Harshada R. Bhangale	PATHOLOGY	HISTOMORPHOLOGICAL STUDY OF UTERUS IN ABNORMAL UTERINE BLEEDING
Dr. Runali D Mendhe	PATHOLOGY	STUDY OF HAEMATOLOGICAL AND BIOCHEMICAL FINDINGS IN PATIENTS OF CHRONIC KIDNEY DISEASE AND IT'S CLINICAL CORRELATION

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-Med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

MAHESH GAJANAN DESHMUKH	OBGY	TRANSABDOMINAL ULTRASOUND ASSESSMENT OF FETAL OCCIPUT - SPINE ANGLE TO PREDICT THE MODE OF DELIVERY
YASHASHREE PRADIP DESHMUKH	OBGY	A STUDY OF UTERINE ARTERY DOPPLER FOR PREDICTION OF PREECLAMPSIA FROM 12 TO26 WEEKS OF GESTATION IN TERTIARY CARE CENTER.
AKASH UTTAMRAO MALVI	OPHTHALMOLOGY	A STUDY TO EVALUATE AND COMPARE VISUAL OUTCOMES AFTER CATARACT SURGERY IN DIABETICS COMPARED TO NONDIABETIC PATIENTS AT A TERTIARY CARE CENTRE.
ANUJA VINAYAK GADGIL	OPHTHALMOLOGY	A CLINICAL STUDY OF SUTURELESS GLUEFREE CONJUNCTIVAL AUTOGRAFT REPAIR IN PTERYGIUM SURGERY.
DESHMUKH KALPANA ARJUNRAO	OPHTHALMOLOGY	STUDY OF EFFECT OF MYOPIA AND AXIAL LENGTH ON PERIPAPILLARY RETINAL NERVE FIBRE LAYER USING SPECTRAL DOMAIN OPTICAL COHERENT TOMOGRAPHY

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

JANBANDHU RAHUL SHANTILAL	ORTHOPEDICS	COMPARATIVE STUDY OF FUNCTIONAL OUTCOME OF FIXATION BY OPEN AND CLOSED METHODS IN DISTAL END RADIUS FRACTURE IN TERTIARY CARE HOSPITAL.
PATIL PARIKSHIT PRATAP	ORTHOPEDICS	TO STUDY FUNCTIONAL OUTCOME OF SURGICAL DECOMPRESSION IN LUMBAR SPINAL STENOSIS IN A RURAL HOSPITAL
VELANKAR SUNEET NITIN	ORTHOPEDICS	STUDY ON EFFICACY AND FUNCTIONAL OUTCOME OF AUTOLOGOUS PLATELET RICH PLASMA INJECTION IN ADHESIVE CAPSULITIS , LATERAL EPICONDYLITIS AND PLANTAR FASCIITIS.
RANGNEKAR PRADNIL KISHOR	PAEDIATRICS	CLINICAL PROFILE OF LOW BIRTH WEIGHT NEONATES ADMITTED IN NICU AT TERTIARY CARE CENTER
SHUKLA SURUCHI RAMPRASAD	PAEDIATRICS	PROSPECTIVE STUDY OF CLINICAL OUTCOME OF EARLY DISCHARGED VERY LOW BIRTH WEIGHT BABIES FROM NICU AT WEIGHT BETWEEN 1300GMS TO 1800GMS.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

KAMBLE PRIYANKA SHASHIKANT	PATHOLOGY	THE STUDY OF FINE NEEDLE ASPIRATION CYTOLOGY OF HEAD AND NECK REGION LYMPHADENOPATHY WITH ITS HISTOPATHOLOGIC CORRELATION IN TERTIARY CARE HOSPITAL.
SHAIKH MUJAHID KHADARSAB	PSYCHIATRY	A STUDY OF ASSOCIATION OF SERUM MAGNESIUM LEVELS WITH THE SEVERITY OF ALCOHOL WITHDRAWAL SYNDROME IN HOSPITALISED PATIENTS IN A TERTIARY CARE HOSPITAL.
YADAV GOVIND UDHAVRAO	PSYCHIATRY	STUDY OF PREVALENCE AND CHARACTERIZATION OF DEPRESSION IN SCHIZOPHRENIA IN A TERTIARY CARE CENTER.
BHARAPURIA KANISHKA RAVI	RADIOLOGY	Study of various patterns manifested by COVID 19 infection on Chest CT scan and importance of early chest CT scan in COVID 19 in tertiary care hospital.
BHOSALE ABHIJEET DNYANESHWAR	RADIOLOGY	To stucy the role of magnetic resonance imaging in diagnosis of spine disorders in farm workers attending tertiary care hospital in jalgaon kh.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

SHEIKH MOHAMMAD ZAINUL	RADIOLOGY	To study the role of ultrasonography in the diagnosis of bleeding per vaginum,in the first trimester of pregnancy.
KALBANDE PRAJAKTA PRAKASH	DERMATOLOGY	STUDY OF VARIOUS CLINICAL PATTERNS OF ADVERSE CUTANEOUS DRUG REACTIONS AT DERMATOLOGY OUT PATIENT DEPARTMENT IN A TERTIARY CARE CENTRE
SHAIKH MUBINA IRFAN	DERMATOLOGY	Clinico epidemiological study of Herpes zoster and post herpetic neuralgia and its impact on quality of life
ANISH AVINASH JOSHI	SURGERY	COMPARATIVE STUDY OF EFFICACY OF AUTOLOGOUS PLATELET RICH PLASMA WITH SALINE DRESSING IN DIABETIC FOOT ULCER BY EXAMINING NEOVASCULARIZATION ON BIOPSY
FARKE VAIBHAV BALASAHEB	SURGERY	Study of etiology and management of peritonitis at Tertiary care hospital
MANKAR SHUBHAM SHRIKRUSHNA	SURGERY	SPECTRUM OF DISEASES MANAGED BY LAPAROSCOPY AND ITS OUTCOME AT TERTIARY CARE CENTRE

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-5, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

SHRIYASH KONDIBA SONAWANE	SURGERY	Study Of Management and Outcome of Acute Obstructive Uropathy Due To Calculus In A Tertiary Care Centre
SIRPURAM VARUNDEV ASHOK	SURGERY	EFFECT OF FLAP FIXATION TECHNIQUE ON SEROMA FORMATION AND ITS COMPLICATIONS IN PATIENTS UNDERGOING BREAST CANCER SURGERY AT A TERTIARY CARE CENTER.
LANGADE SUSHIL SURESH	PULMONARY MEDICINE	The study of correlation of C- reactive protein , lactate dehydrogenase, serum ferritin and D - dimer with CT score of covid patiets and outcome in dedicated COVID hospital
SAMADHAN DATTATRAYA BAHEKAR	PULMONARY MEDICINE	Study of post COVID 19 pulmonary complications at a tertiary care center - Prospective observational study.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavar Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)/2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2355648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

Name of PG student	Department	Thesis Title
DESHPANDE HARSHA SANJAY	ANAESTHESIA	TO STUDY THE EFFECT OF INTRAVENOUS MAGNESIUM SULPHATE IN ATTENUATING THE HEMODYNAMIC RESPONSE DURING LARYNGOSCOPY AND INTUBATION IN PATIENTS REQUIRING GENERAL ANAESTHESIA AT A TERTIARY CARE CENTRE.
KELGAONKAR VIJAYA VIVEK	ANAESTHESIA	A COMPARATIVE STUDY OF DEXAMETHASONE AS AN ADJUVANT TO LOCAL ANAESTHETIC DRUG FOR SUPRACLAVICULAR BLOCK WITH PLACEBO IN A TERTIARY CARE CENTER
PRAJAKTA PRAKASH SHILAHAR	ANAESTHESIA	COMPARATIVE STUDY BETWEEN FENTANYL AND BUPRENORPHINE AS AN ADJUVANT TO HYPERBARIC BUPIVACAINE IN SUBARACHNOID BLOCK FOR INFRA UMBILICAL SURGERIES
SONONE SHIVAJI DILIP	ANAESTHESIA	TO COMPARE EFFECT OF 0.75% ROPIVACAINE WITH 0.5% BUPIVACAINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB SURGERIES IN TERTIARY CARE CENTRE.
HARSHAL VASUDEO MAHAJAN	ENT	A COMPARATIVE STUDY OF ENDOSCOPIC SEPTOPLASTY OVER CONVENTIONAL SEPTOPLASTY IN TERTIARY CARE CENTER.
KHANDAGALE SHRUTI SHAILENDRA	ENT	A COMPARATIVE STUDY BETWEEN GRAFTS OF TRAGAL CARTILAGE, TEMPORALIS FASCIA LATA IN PATIENTS POSTED FOR REVISION TYMPANOPLASTY.

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.

Godavari Foundation's

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL,

Recognized by Medical Council of India, Approved by Central Govt. of India, New Delhi,
Letter no. MCI-34(41)-2012-med./158127, dated 05/02/2013
Affiliated to Maharashtra University of Health Sciences, Nashik [College Code-1306]
Jalgaon-Bhusawal Road, NH-6, Jalgaon Kh, Tal. & Dist. Jalgaon 425309
Tel. No. (0257)2366657, 2366678 Fax No. 0257-2366648
Email ID : dupmcj@yahoo.in Web Site : www.dupmc.ac.in

KAMELI MOHAMMAD JUNAID RAFEEQUE AHMAD	MEDICINE	COMPARATIVE STUDY OF ECG AND CORONARY ANGIOGRAPHIC FINDINGS WITH ACUTE CORONARY SYNDROME IN DIABETIC AND NON-DIABETIC PATIENTS IN TERTIARY CARE CENTRE
KOTECHA TEJAS KUNDAN	MEDICINE	STUDY OF CLINICAL PROFILE OF PATIENTS WITH HYPONATREMIA IN TERTIARY CARE HOSPITAL
NANDEDKAR ADITYA MAHADEV	MEDICINE	THE STUDY OF SERUM MAGNESIUM AND VITAMIN D3 IN TYPE 2 DIABETES MELITUS AND ITS CORRELATION WITH CORONARY ARTERY DISEASE
PRIYANKA ASHOK BHALKE	MEDICINE	BACTERIAL SPECTRUM OF ASCITIC FLUID IN ALCOHOLIC LIVER DISEASE PATIENT ON ADMISSION AND ITS CORRELATION WITH SERUM ASCITIC ALBUMIN GRADIENT.
WAGAJ SUSHANT PRAKASH	MEDICINE	A STUDY TO ESTIMATE PREVALENCE OF ANAEMIA IN ACUTE AND CHRONIC INFLAMMATION IN PATIENTS ATTENDING TERTIARY CARE HOSPITAL.
DONGARWAR AKASHKUMAR SHALIKRAM	OBGY	AN OBSERVATIONAL STUDY OF INTRAOPERATIVE DIFFICULTIES IN REPEAT CAESAREAN SECTION COMING TO TERTIARY CARE HOSPITAL

DR. ULHAS PATIL MEDICAL COLLEGE & HOSPITAL JALGAON

Dean
Dr.Ulhas Patil Medical College
& Hospital, Jalgaon Kh.