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

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

Dr. G. N. Singh
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan

Re registration of I

File No. EC/21/000320

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

सत्यमेव जयते

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

VENUGOPAL GIRDHARILAL SOMANI

(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

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)

सत्यमेव जयते

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 Bhavsar	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

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/852/Inst/MH/2016/RR-21

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee, Dr. Ulhas Patil Medical College and Hospital, 1st Floor, College Building, DUPMCH, Jalgaon- 425309, Maharashtra, India. Contact No.: 0257-2366657 Fax No.: 0257-2366648 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

GREHANE AI SOMANI

Central Licencing Authority
Stamp

Place: New Delhi

Date: 18-NOV-2021