



सत्यमेव जयते

File No. EC/22/000018

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: 31-Jan-2022

To  
The Chairman  
KEM Hospital Research Centre Ethics Committee  
KEM Hospital Research Centre  
TDH Building, 3<sup>rd</sup> floor, Room No -303  
Sardar Moodliar Road, Rasta Peth  
Pune, Maharashtra - 411011 India

Subject: Ethics Committee Re-Registration No. ECR/272/Inst/MH/2013/RR-22 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2022/13389 dated 15-Jan-2022 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/272/Inst/MH/2013/RR-22. The said registration is subject to the conditions as mentioned below:-



Yours faithfully  
VENUGOPAL G SOMANI  
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SOMANI  
Digitally signed by VENUGOPAL G SOMANI  
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(Dr. V.G. Somani)  
Drugs Controller General (I) &  
Central Licensing Authority

#### Conditions of Registration

1. The registration is valid from 31-Jan-2022 to 30-Jan-2027, 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, 1940 and 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.

FORM CT-02

(See rules 8, 9, 10 and 14)

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

Registration No. ECR/272/Inst/MH/2013/RR-22

The Central Licencing Authority hereby registers and permits KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH Building, 3<sup>rd</sup> floor, Room No -303, Sardar Moodliar Road, Rasta Peth, Pune, Maharashtra - 411011 Contact No.: 020-66037335 Fax No.: 020-26065603 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.

VENUGOPAL  
G SOMANI

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CONTROL ORGANIZATION, ou=DRUGS  
CONTROLLER GENERAL (INDIA),  
pseudonym=112046a34e21727bach255748  
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serialNumber=e97f241aa0c0bba41522525ff  
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Date: 2022.01.31 16:24:59 +05'30'

Central Licencing Authority  
Stamp

Place: New Delhi

Date: 31-JAN-2022



**ECR/113/KEM/Inst/MH/2013/Re-Registration-2022**

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

Dated: **20 AUG 2024**

To,

**The Chairman/Member Secretary,  
KEM Hospital Research Centre Ethics Committee  
KEM Hospital Research Centre TDH Building,  
3rd floor, Room No -303 Sardar Moodliar Road,  
Rasta Peth Pune, Maharashtra - 411011India**

**S u b j e c t :** Ethics Committee Registration No. **ECR/272/Inst/MH/2013/RR-22** amendment to the composition of the Ethics Committee-regarding.

**Sir/Madam,**

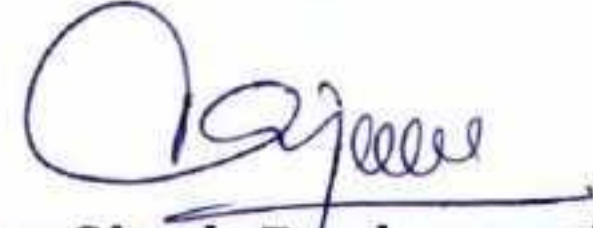
Please refer to your application submitted to this Directorate for change in composition of the Registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Registration number **ECR/272/Inst/MH/2013/RR-22** dated **31.01.2022** valid until **30.01.2027** is hereby amended as follows, with all conditions of the Registration Certificate initially granted to you, remaining the same including the condition that **"the Ethics Committee shall review and accord approval to Clinical Trial and BA/BE Study protocol of new drugs and also conduct periodic review of the studies as per the New Drugs and Clinical Trial Rules, 2019"**.

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Mandeep S Chadha	MBBS (MD - General Medicine)	Chairperson
2.	Dr. Ranjana V Mundhe	BHMS (MD- Homeopathy, PGDCR)	Member Secretary
3.	Dr. Sudha V Kanitkar	MBBS (MD- Pharmacology)	Medical Scientist
4.	Dr. Kalpana U Shah	MBBS (MD- Pharmacology)	Medical Scientist
5.	Dr. Uma P Divate	MBBS (MD - General Medicine )	Clinician
6.	Dr. Valentine Lobo	MBBS, MD, (Medicine), DNB, Nephrology	Clinician
		BA (Post Graduate	

7.	Ms. Sanghmitra Bhattacharjee	Diploma in Public Relations)	Lay Person
8.	Adv. Naresh Singh	BSL (LLB)	Legal Expert
9.	Dr. Shilpa Karvande	PhD, Public Health	Social Scientist
10.	Ms. Perveen Bharucha	BA (MA-Medical Social Work)	Member
11.	Ms. Savita Kanade	B.Sc (M.Sc.- Anthropology, MPS)	Social Scientist
12.	Dr. Deepa Paturkar	PhD., LL.M	Legal Expert
13.	Mrs. Veena Thadani	MSc(Zoology), BEd(Science & English )	Lay Person

Yours faithfully



**(Dr. Rajeev Singh Raghuvanshi)**  
**Central Licensing Authority**

**KEM Hospital Research Centre**

Inward No. 263 Date. 23/8/24

Admin/Accounts/Project Officer \_\_\_\_\_

Director Research 