



Government of India  
Ministry of Health & Family Welfare  
Department of Health Research  
(National Ethics Committee Registry for Biomedical and Health Research)

2nd Floor, IRCS Building,  
Red Cross Road, New Delhi – 110001  
Date : 15-Nov-2022

**FORM CT-03**

(See rules 17 and 18)

**GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH**

Registration No. **EC/NEW/INST/2022/AP/0198**

The designated authority hereby registers and permits SJDC-INSTITUTIONAL ETHICS COMMITTEE , ST.JOSEPH DENTAL COLLEGE AND HOSPITAL ST.JOSEPH DENTAL COLLEGE AND HOSPITAL , City-ELURU, District-West Godavari - Andhra Pradesh - 534003 Contact No.: 08812277583 Fax No.: 08812277767 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 IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place : New Delhi

Date : 15-Nov-2022

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Designated Registration Authority  
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**Government of India**  
**Ministry of Health & Family Welfare**  
**Department of Health Research**  
**(National Ethics Committee Registry for Biomedical and Health Research)**

2nd Floor, IRCS Building,  
Red Cross Road, New Delhi – 110001  
Date : 15-Nov-2022

To

**The Chairperson**

**SJDC-INSTITUTIONAL ETHICS COMMITTEE**

**ST.JOSEPH DENTAL COLLEGE AND HOSPITAL ST.JOSEPH DENTAL COLLEGE AND HOSPITAL, City-  
ELURU, District-West Godavari - Andhra Pradesh - 534003**

Subject: Ethics Committee Registration No. EC/NEW/INST/2022/AP/0198 issued under New Drugs and Clinical Trials Rules, 2019

Sir/Madam,

Please refer to your file No. EC/NEW/INST/2020/1176, dated 07-Sep-2020 submitted to this National Ethics Committee Registry for Biomedical and Health Research (NECRBHR, Department of Health Research) for the Registration of Ethics committee.

Please find the enclosed registration of the Ethics committee in form CT-03 vide Registration No. EC/NEW/INST/2022/AP/0198, dated 15-Nov-2022. The said registration is subjected to the conditions as mentioned below.

Yours faithfully,  
DAULAT  
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(D R Meena)  
Director

### **Conditions of Registration**

The following include few of the conditions to be followed by the Ethics Committees (ECs) registered with the Designated Authority (NECRBHR, DHR).

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Designated Authority, NECRBHR, DHR. The EC has been registered for the purpose of reviewing Biomedical and Health Research. For Clinical Trials review, registration with CDSCO is required.
2. This certificate is issued to you on the basis of declaration/submission made by you.
3. An institution or organization or any person shall conduct any Biomedical and Health Research with the approval of the Ethics Committee registered under rule 17, Chapter IV of New Drugs and Clinical Trials Rules 2019.
4. The Ethics Committee should be constituted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 as may be specified by the Indian Council of Medical Research from time to time and shall function in accordance with said guidelines.
  - a) EC composition should be as follows:
    - i) ECs should be multi-disciplinary and multi-sectoral.
    - ii) There should be adequate representation of age and gender.
    - iii) Preferably 50% of the members should be non-affiliated or from outside the institution.
  - iv) The number of members in an EC should preferably be between 7 and 15 and a minimum

of five

members should be present to meet the quorum requirements.

- v) The EC should have a balance between medical<sup>1</sup> and non-medical members/technical<sup>2</sup> and non-technical members, depending upon the needs of the institution.
- b) Composition of the said Ethics Committee is as per the Annexure-I.
- c) Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Designated Authority NECRBHR, DHR.

5. The Chairperson of an Ethics Committee (EC) should be a non-affiliated person from any background with prior experience of having served/serving in an EC whereas the Member Secretary should be a staff member of the Institution and should have knowledge and experience in clinical research and ethics.

6. EC Members should be conversant with the provision of New Drugs and Clinical Trials Rules 2019, ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and other regulatory requirements to safeguard the rights, safety and well-being of the human participants.

7. Conflict Of Interest (COI) should be declared and managed in accordance with Standard Operating Procedures (SOPs) of the EC. EC members are responsible for declaration of COI to the Chairperson, if any, at each meeting. The member who has declared COI should withdraw from the EC meeting while the research proposal is being discussed and the quorum must be rechecked and it should be recorded in the minutes of meeting.

8. In case of studies involving vulnerable population and stigmatized populations, the Ethics Committee, may associate with representatives of patient groups and subject experts who are not its members, in its deliberations but such experts shall not have voting rights, if any.

9. Ethics Committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing to the Principle Investigator.

10. The EC should continuously evaluate progress of ongoing proposals, review Serious Adverse Event (SAE) reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activity.

11. The function, proceedings of Ethics Committee and maintenance of records shall be as per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of Biomedical and Health Research study, as the case may be, for a period of three years after completion of such study.

12. Where any SAE occurs to a study participant during its conduct of Biomedical and Health Research, the Ethics Committee shall analyse the relevant documents pertaining to such event and maintain reports and comply with the provisions of chapter – IV, New Drugs and Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017.

13. The Ethics Committee shall undertake proper causality assessment of Serious Adverse Events (SAE's) with the help of subject expert's wherever required, for deciding relatedness and quantum of compensation as per condition no. (12) mentioned above.

14. 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.

15. 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.

16. The EC should be competent and independent in its functioning. The institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support, etc.. Ethics Committee records will be maintained.

17. The Ethics Committee shall allow experts/officials authorized by Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research study and provide adequate replies to any query raised by such experts/officials, as the case may be, in relation to the conduct of Biomedical and Health Research.

18. When Ethics Committee fails to comply with any provisions of the New Drugs & Clinical Trials Rules 2019 and ICMR National Ethical Guidelines 2017, the Designated Authority 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 Designated Authority, NECRBHR, DHR may take one or more actions specified under provision of Rule 18, Chapter IV of New Drugs and Clinical Trials Rules 2019.

19. To maintain independence, the Head of the Institution should not be part of the EC but should act as an appellate authority to appoint the committee, including Chairperson or to handle disputes. The appointment letter issued to all members should specify the Terms of References (TORs) and should include, at the minimum, the role and responsibility of the member in the committee, duration of appointment and conditions of appointment.

20. The Chairperson and Member Secretary could have dual roles in the EC as they could fulfil a role based on their qualifications (i.e. clinician, legal expert, etc.) in addition to taking on the role of Chairperson or Member Secretary.

21. The Institutions could have subcommittees such as SAE subcommittee or expedited review committee which should be a part of the main committee and comprise Chairperson/ Member Secretary and one to two appropriate designated members of the main EC as defined in the SOPs.

22. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements and can have the same TORs as regular members and can attend meetings in the absence of regular members.

23. The Ethics Committee shall make an application for renewal of registration in Form CT-01 along with documents as specified in sub-rule (2) at least ninety days prior to the date of the expiry of its final registration: Provided that if the application for renewal of registration is received by the authority designated under sub-rule (1), ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on the application: Provided further that fresh set of documents shall not be required to be furnished, if there are no changes in such documents furnished at the time of grant of final registration, and if the applicant renders a certificate to that effect indicating that there is no change.

\*1 Medical members are clinicians with appropriate medical qualifications.

\*2 Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example: - Social Science.

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**Government of India**  
**Ministry of Health & Family Welfare**  
**Department of Health Research**  
**(National Ethics Committee Registry for Biomedical and Health Research)**

2nd Floor, IRCS Building,  
 Red Cross Road, New Delhi – 110001  
 Date : 15-Nov-2022

Composition of the Ethics Committee:

S.No.	Name of Member	Qualification	Role/Designation in EC
1	Mr. ABRAHAM DOMATHOTI	BSc (M.Sc)	Chair Person
2	Dr. SLEEVA RAJU NAGOTHU	BDS (MDS)	Member Secretary
3	Dr. PRAKASH RAO N	MBBS (MD ANAESTHESIOLOGY)	Basic Medical Scientist
4	Dr. CHANDRA SEKHARA RAO RAYALA	BDS (MDS)	Clinician
5	Mr. JOSEPH THAMBI DEVARAPALLI	BA-Sociology (MA,MPhil)	Social Scientist
6	Mr. AJITRAJ TADEPALLI	Other (MA)	Legal Expert
7	Mr. AVINASH RAJU CHUKKA	BA (MA, B.Ed)	Lay Person
8	Ms. SHAILAJA KALLU	Other (M.PHARMACY)	Member
9	Dr. PRAVEEN KUMAR N	BSc (M.SC. PH.D.)	Scientific Member
10	Mr. MURALI KRISHNA K	BSc (Not Applicable)	Other Supporting Staff
11	Ms. SUSEELA G	BA (Not Applicable)	Other Supporting Staff

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 (D R Meena)  
 Director



**Government of India  
Ministry of Health & Family Welfare  
Department of Health Research**

2nd Floor, IRCS Building,  
New Delhi - 110001  
Dated : 19-Nov-2020

**Provisional Certificate**

**Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).**

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter-IV of the New Drugs and Clinical Trials Rules, 2019.

**Name :** SJDC-INSTITUTIONAL ETHICS COMMITTEE  
**Address :** ST.JOSEPH DENTAL COLLEGE AND HOSPITAL, ST.JOSEPH DENTAL COLLEGE AND HOSPITAL, DUGGIRALA ELURU, West Godavari, Andhra Pradesh - 534003  
**Contact No:** 08812277583  
**Fax :** 08812277767

2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).

3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.

4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

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(Anu Nagar)  
Joint Secretary  
Department of Health Research  
Designated Authority