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# Standard Operating Procedures

# For

# Institutional Ethics Committee

**LENORA INSTITUTE OF DENTAL SCIENCES, RAJANAGARAM, RAJAHMUNDRY-533294,A.P.**

**I. Short Description of SOP.**

The following may be called as "Standard Operating Procedures for the Institutional Ethics Committee (IEC) of Lenora Institute of Dental Sciences, Rajahmundry".

**II. Adoption of SOP.**

Lenora Institute of Dental Sciences, Rajahmundry herein after referred to as "LIDS IEC" has adopted these written Standard Operating Procedures (SOP/SOPs) to ensure the protection of the rights and welfare of human participants in biomedical, experimental and behavioral research conducted at LIDS, Rajahmundry

**III. Objectives of SOP.**

The objective of these Standard Operating Procedures of the Institutional ethics committee (IEC) of Lenora Institute of Dental Sciences, Rajahmundry is to maintain effective functioning of the IEC and to ensure quality and consistency in review of clinical research proposals and to follow the ICMR and national ethical guidelines for biomedical research on human subjects.

**IV. Authority for constituting the IEC.**

The Principal, LIDS, Rajahmundry will appoint the Chairperson and all the committee members

based on their competence, experience and integrity by request (Annexure-1). Members will confirm their acceptance to the Principal by providing all the required information for membership (Annexure-2). The Chairperson will furnish any information or report to the Principal, Lenora Institute of Dental Sciences, Rajahmundry when required.

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Member Secretary,
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**V. Role and Responsibilities of IEC.**

The IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all actual and potential research participants before approving the research proposals. The goals of research, however important, should never be permitted to override the health and wellbeing of the human participants. The IEC will ascertain whether all the cardinal principles of research ethics viz., **Autonomy, Beneficence, Non – maleficence, Respect for Free and Informed Consent, Respect for Human Dignity, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality and Justice are taken care of in planning, conducting and reporting of the proposed research.**

IEC will review the proposals before the commencement of the study as well as review periodically until the completion of the study through appropriate well documented procedures.

The mandate of the IEC shall be to review all research projects to be conducted in the Institution involving human beings directly or indirectly, irrespective of whether the research project is funded or non-funded, and if funded, then irrespective of the funding agency. In case IEC revokes its approval accorded to a trial protocol, it will record the reasons for doing so and at once communicate such a decision to the Investigator as well as to the Licensing Authority.

**VI. Composition of IEC:**

IEC will be a multidisciplinary and multi-sectorial body in composition and independent. The number of members of the Review Board may range from 7 to 15. The chairperson/ Chairman of the IEC will be from outside the Institution to maintain the independence of the Committee. The Member Secretary will belong to the same Institution and will conduct the business of the Committee. Other members will be a mix of Medical/Dental , non-medical, legal, scientific and nonscientific persons and may also include members of public to reflect the different points of view.

The IEC of LIDS, Rajahmundry will include:

1. Chairperson –from outside the institute
2. Member Secretary – from within the institute

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3. Basic medical scientist -One from pharmacy
4. Clinicians (Dental)- Two Clinicians affiliated to the Institution
5. Legal expert- from out side
6. Social scientist / Philosopher/Ethicist/Theologian- Nonaffiliated to the Institution
7. Lay person (non-medical background) from the community

Compulsorily one women member should be present in the IEC. A subcommittee of the main IEC may be formed by the chairman of IEC to review research proposals (Synopsis) of Post-Graduate students and ICMR STS Undergraduate/Post Graduate students.

**VII. Requirements for IEC Membership**

1. All members will serve for a period of 3 years. New members will be included in the IEC in such a way that there will be a mix of recently included members and members with some years of experience.
2. During the term, Principal, Lenora Institute of Dental Sciences, in consultation with the Chairman can disqualify any member, if the contribution is not adequate and/or there is long period of non-availability of the members.
3. A member can tender resignation of his office of membership from the IEC to the Principal, Lenora Institute of Dental Sciences, through the Chairperson after serving one month advance notice.
4. Principal Lenora Institute of Dental Sciences, can replace the member of IEC as and when required.
5. Each member is required to sign the declaration and confidentiality agreement regarding IEC activities (Annexure -3).
6. Conflict of interest should be declared by members of the IEC prior to review meeting.

**VIII. Conduct of IEC meetings**

The Chairman will conduct all meetings of the IEC. In the absence of the Chairman, he can nominate one person among the EC members to act as Chairperson to conduct the meeting with the same powers. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. The Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson.

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**IX. Terms of reference:**

Terms of reference will be maintained in the office of IEC. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure,

D. Frequency of meetings,

The SOPs will be updated periodically based on the changing requirements. IEC would appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country.

**X. Resignation and Disqualification of Members:**

**Resignation**: LIDS 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.

**XI. 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 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.

**XII. Functions of the Member secretary**

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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 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 ensure adherence of IEC functioning as per SOPs

**XIII. Roles and Responsibilities of IEC members**

1. To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. To monitor Serious Adverse Event reports and recommends appropriate action(s)
4. To review the progress reports and monitor ongoing studies as appropriate.

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5. To evaluate final reports and outcomes.

6. To review clinical trial agreement, Insurance policy and informed consent document specifically by the **legal expert** of the IEC.

7. To maintain confidentiality of the documents and deliberations of IEC meetings.

8. To declare any conflict of interest.

9. To sign the Confidentiality / Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

10. To participate in continuing education activities in biomedical ethics and biomedical research.

11. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat

12. To provide an updated CV when requested for by the IEC secretariat

13. To carry out the work delegated by Chairperson, Member-secretary.

14. To assist Chairperson, Member-secretary in carrying out IEC work as per SOPs

**XIV. Quorum requirements:**

As per ICMR guidelines, the new drug and clinical trials, Rules 2019,

*A minimum of five (05) members should be present.

*The quorum should include both medical (dental), non medical (dental)

*Minimum one (01) non-affiliated should be part of the quorum

*No decision is valid without fulfillment of the quorum

**XV. Training of the IEC Members in Research Ethics:**

1. All relevant information on ethics will be brought to the attention of the members of IEC by the Member Secretary.

2. IEC Members will be encouraged to attend national and international training programs/conferences/seminars in the field of research ethics to help in improving the quality of research protocols/ethics committee submissions and review.

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3. Members should be trained in human research protection, EC functions and SOPs, and should be conversant with ethical guidelines.

4.Any change in the relevant guidelines or regulatory requirements should be brought to the attention of all EC members.

**XVI. Review Procedure**

1. Meetings of IEC shall be held on scheduled intervals as prescribed (once in 3 months, for which the dates will be decided at the end of previous meeting). Additional meetings will be held as and when necessary.

2. The proposals will be sent to members at least 2 weeks in advance.

3. Decisions will be taken by consensus after discussions, and voting will be done if necessary.

4. PI should be available during the meeting and may be invited to offer clarifications.

5. Independent consultants/Experts may be invited to offer their opinion on specific research proposals.

6. The decisions of the meeting shall be recorded in the minutes book and shall be confirmed during the next meeting with signature of Chairperson .

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