

SETHU INSTITUTE OF TECHNOLOGY

Institutional Ethics Committee

Standard Operating Procedures

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Establishing and Constituting the Institutional Ethical Committee (IEC)

PROCEDURE

- * The Director R &D Sethu Institute of Technology will select and nominate the Chairperson, Members and Member Secretary for IEC.
- * The Head of the Institution will invite the members to join Ethical Committee by sending official request letter.
- * Members will confirm their acceptance to the Head of the Institution by providing all the required information for membership.
- * The Director R &D Sethu Institute of Technology will ensure that the IEC is established in accordance with the applicable laws and regulations of the state, country and in accordance with the value and Principles of communities they serve
- * The Director R &D will designate and instruct Chairperson of IEC or his representative to conduct the regular proceedings of IEC for the Institute.
- * At regular intervals, Director R &D will review the functioning of IEC

Organization of the IEC

1. Chairperson – from outside the institution
2. One persons from basic medical science area
3. Two clinicians from various institutions
4. One legal expert or retired judge
5. One social scientist /representative of NGO
6. Two Academic Person
7. One lay person from the community
8. Member secretary

Procedure for appointing members for the IEC

PROCEDURE

1. The Director R&D Sethu Institute of Technology in consultation with Head of the institution will nominate the members of IEC, who have the qualification and experience to review and evaluate the scientific, medical and ethical aspects of the proposed study.
2. When needed, IEC will invite subject experts to offer their views.
3. The appointment of an IEC member will be for 1 year.
4. The Director R&D may renew the appointment on the basis of the member's contribution.
5. During the term, Director R &D in consultation with the Head of the institution can disqualify any member if, the contribution is not adequate and/or there is long period of (member) non-availability.
6. Member will have the right to discontinue from membership of IEC after giving written notice at least one month in advance.
7. The Director R&D can replace the member of IEC as and when required.
8. Each member is required to sign the declaration and Confidentiality agreement regarding IEC activities.
9. The Director R&D can nominate IEC members to undergo orientation programme in national and international developments in ethics.

Procedure for convening and conducting IEC meetings

PROCEDURE

1. The Member Secretary in consultation with the Head of the institution may convene the IEC meeting once in every three months or earlier.
2. Additional review meetings can also be held with short notice as and when required.
3. Meetings will be planned in accordance with the need of the work load.
4. All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.
5. All the proposals will be received at least three weeks before the meeting, checked for completeness as per the check list initially by the IEC Members subsequently by the member secretary (through a nominated person) using the evaluation form .
6. Members will be given not less than 10 days time in advance to review study proposals and the relevant documents.
7. Minutes of the IEC meetings, all the proceedings and deliberation will be documented.
8. Signatures of the Head of the institution and the Member Secretary will be obtained on the minutes of the meeting document. The minutes will be circulated to all the guides /HODs in case of student proposals.
9. Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.
10. Independent experts may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement. They will not have a role in decision making.

Procedure for submission of research project for review by Ethical Committee

1. Applicable to Principal Investigators from Sethu Institute of Technology -IEC
2. All investigators are responsible for implementing this SOP. Every protocol submitted for review to IEC must contain number, version and date. All the research proposals must be submitted in the prescribed application form, duly filled, along with all necessary documents for the review.

PROCEDURE

1. The Project Investigator has to submit an application in a prescribed format along with study protocol and other study related documents necessary for review of the IEC .All research proposals must be submitted in English language only.
2. Application can be submitted to the office of the Member Secretary, Sethu Institute of Technology -IEC
3. All the proposals and documents must be submitted at least three weeks in advance from the scheduled date of IEC meeting
4. Three copies of study proposal (with all documents) must be submitted for Regular Ethics Committee along with application form duly signed and dated by the investigator(s).
5. Receipt of the application will be acknowledged by the IEC Cell
6. Every application will be allotted an IEC registration number to be used for all future correspondence and reference

Procedure for initial scrutiny of proposals

PROCEDURE

1. Every proposal will be collected and compiled by the Institute Ethical Committee Cell.
2. IEC members nominated by the Director R&D Sethu Institute of Technology will verify the proposals for completeness as per the checklist.
3. In case of incomplete data, the investigators will be informed by the IEC Cell after consulting the Member Secretary to make the necessary corrections and to resubmit.

Procedure for reviewing the research proposals

PROCEDURE

1. Every proposal will be sent not less than 10 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.
2. All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
3. The IEC review will be done through formal meetings.
4. However in case of a proposal awaiting review on an urgent basis, review may be considered for decision through circulation of proposals to members after obtaining prior permission from the Chairperson regarding the same.
5. Expert opinion of additional members should be obtained for further evaluation of the proposals.

Procedure for decision making regarding the research

PROCEDURE

In making decision on application for the ethical review of any research proposal, IEC will consider the following:

1. Member having a conflict of interest will indicate to the Chairperson prior to the review of application and same will be recorded in the minutes.
2. Where there is a conflict of interest, member will withdraw from the decision making procedure.
3. A decision will only be taken when sufficient time has been allowed for the review and discussion of an application in the absence of non-members (e.g. Investigator) from the meeting.
4. Decision will only be taken at meetings where a quorum (Three in a committee of 5) is complete.
5. Decision will be taken only after reviewing a complete application with all the required documents necessary for proposal.
6. Only IEC members who participated in review and discussion will participate in decision making.
7. Wherever possible, the decision will be arrived through consensus and not by vote, but when a consensus appears unlikely voting can be resorted to.
8. Decision will specify the conditional decision if any, with clear suggestions and re-review procedure
9. Rejection of proposal will be supported by clearly stated reasons.

Procedure for communicating the decision of IEC to the Investigator

PROCEDURE

A decision of the IEC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format .A certificate of approval will be sent to the applicant within 2 weeks. All the approvals will be valid for only one year or for the duration of the project whichever is less. Investigator has to get his or her project re-approved after three years if necessary.

The communication of the decision will include:

- A. Name and address of IEC.
- B. The date and place of decision.
- C. The name and designation of the applicant.
- D. Title of the research proposal reviewed.
- E. The clear identification of protocol no., version no., date, amendment no., date.
- F. A clear statement of decision reached.
- G. Any advice by the IEC to the applicant.
- H. In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re- reviewed.
- I. In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
- J. Signature of the member secretary with date.

Procedure for follow-up of research projects by Ethical Committee

PROCEDURE

1. IEC will review the progress of all the studies for which a positive decision has been reached from the time of decision till the termination of the research.
2. Progress of all the research proposals will be followed at a regular interval of at least once a year.
3. But in special situations, IEC will conduct the follow up review at shorter intervals based on the need, nature and events of research project.
4. All the requirements and procedures for follow up review will be similar to that of initial and main review.

Following instances and events will require the follow-up review:

- Any protocol amendment likely to affect rights, safety or well-being of research subject of conduct of study.
 - Serious or unexpected Adverse Drug Reaction related to study or product, action taken by Investigator, Sponsor and Regulatory Authority.
 - Any event or information that may affect the benefit/risk ratio of the study.
5. A decision of a follow up review will be issued and communicated to the applicant indicating modification/suspension/termination /continuation of the project.
 6. In case of premature suspension /termination, the applicant must notify the IEC of the reasons for suspension/termination with a summary of results.
 7. Applicant must inform the time of completion of study and must send the result summary to IEC.
 8. IEC must receive a copy of final summary of study completed from the applicant

Procedure for Documentation and archiving of documents and Communication of IEC

PROCEDURE

1. All the documents and communications of IEC will be dated, filed and archived in a secure place.
2. Only persons, who are authorized by the Chairperson of IEC will have the access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except agenda) will be retained by any IEC member.
5. At the end of each meeting, every member must return all the research proposals and documents to IEC cell members. They will archive one copy in IEC cell and other copies will be destroyed after one year.
6. Following documents will be filed and archived with proper label on the top of file for easy identification of proposal
7. The constitution, written standard operating procedures of the IEC, and regular (annual) reports.
8. The curriculum vitae of all IEC members.
 - A. A record of all income and expenses if any, of the IEC, including allowances and reimbursements made to the secretariat and IEC members.
 - B. The published guidelines for submission established by the IEC.
 - C. The agenda of the IEC meetings.
 - D. The minutes of the IEC meetings.
 - E. One copy of all material submitted by an applicant.
 - F. A copy of the decision and any advice or requirements sent to an applicant.
 - G. All written documentation received during the follow-up.
 - H. The notification of completion, premature suspension, or premature termination of study
 - I. The final summary or final report of the study.

