# Institutional Ethics Committee (IEC)
# St. Anthony's College
# Shillong – 793001
# (*According to ICMR guidelines*)

**Institutional Ethics Committee (IEC) and its Standard Operating Procedures (SOP)**

***(For biological/biomedical/biotechnological teaching, research and production activity involving the use of animal models and/or human samples/participants)***

## 1. Objective:

The objective of this Standard Operating Procedures (SOP) is to contribute to the effective functioning of the Institutional Ethics Committee (IEC). This is so as to ensure that a proper and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by the Committee. The IEC will ensure that all proposals put forward are as prescribed by the Ethical guidelines of concerned national agencies for biological/biomedical/biotechnological teaching, research and production activity involving the use of animal models and/or human samples/participants.

## 2. Role of IEC

The IEC will review and approve all types of research proposals involving animal models and/or human samples/participants with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well-being of the research subjects.

The IEC will take care that all the cardinal principles of research ethics which are Autonomy, Beneficence, and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk- benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study up to and after completion of the study through appropriate well documented procedures. For example, annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the IECs will be to review all research projects involving animal models, and / or human samples/participants to be conducted in the Institute, irrespective of the funding agency. The role of IEC can be modified, as and when necessary, in conformity with national guidelines.

**3. Composition of IEC**

1. Chairperson
2. Deputy Chairperson
3. Member-Secretary
4. Clinicians (Medical Profession)
5. Veterinary doctor
6. Legal expert
7. Social Scientist / or person from Social Science background
8. One lay person from the community
9. Science faculty (three to five members) involved in biological/biomedical/biotechnological research

If required, subject experts could be invited to offer their views.

Chairperson may constitute sub-committee(s), if required, for any specific purposes.

**4. Authority under which IEC is constituted:**

The Institutional Head constitutes the IEC.

**5. Membership:**

a. The duration of membership shall be for 3 years.
b. A member can be replaced in the event of death or long-term non-availability, resignation or for any action not commensurate with the responsibilities related to IEC..
c. A member can tender resignation from the committee with proper reasons to do so.
d. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
e. Conflict of interest, if any, should be declared by members of the IEC.

**6. Quorum:**

A minimum of five members are required to form a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

**7. Offices:**

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson will conduct the meeting. The Member Secretary is responsible for convening the meetings, maintaining the records and communicating with all concerned. She/he will prepare the minutes of the meetings and get it approved by the Chairperson before communicating to the researchers with the approval of the Chairperson.

## 8. Application Procedures:

a. All applications should be submitted in the prescribed form (10 copies).
b. All relevant documents (one copy each) should be enclosed with the application form.
c. Required number of copies of the application along with the documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators should be forwarded by the Head of the Departments / Centres to the IEC.
d. The date of meeting will be intimated to the applicant, who will be expected to give clarifications to the Committee, if necessary.
e. The decision of IEC will be communicated to the applicant(s) in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication.

## 9. Prescribed Application Form for Clearance of Research Project by IEC

1. (a) Name of the Principal Investigator with designation:
   (b) Name(s) of the Co-Investigators:
2. Name of the Department/Centre where research will be conducted:
3. Approval of the Department/Centre obtained: Yes / No
4. Protocol of the proposed research involving animal models and/or human samples/participants:
5. Ethical issues in the study and plans to address these issues:
6. Copies of Proforma/Case report forms/Questionnaires/Follow-up cards, etc.:
7. A brief statement explaining the process of obtaining Informed consent:
   (Please enclose a copy/format of informed consent form in local language and its translation in English).
8. For any drug/device trial, all relevant publications/pre-clinical data and clinical trial data from other centres within the country and/or other countries, if available:
9. Curriculum vitae of all the investigators with relevant publications in last five years:
10. Regulatory clearances (other than IEC of St. Anthony's College) required, if any:
    If 'Yes', enclose the Clearance Certificate:
11. Source of funding and financial requirements for the project:
12. An agreement to report only Serious Adverse Events (SAE) to IEC: Yes / No
13. Statement of conflict of interest, if any:
14. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants such as the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research:
15. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants:
16. Any other information relevant to the study:

I/we _____ Department(s) _____ of hereby declare that the statements given in this application are true to the best of my/our knowledge and belief, and agree to comply with the guidelines/decisions of IEC,

St. Anthony's College, Shillong as well as the ethical guidelines of relevant national agencies for conducting research on animal models and/or human samples/participants.

| | |
|---|---|
| Signature of Principal Investigator (PI) | Signature of Head(s) of the Department(s) |
| Date: | Date: |
| Place: | Place: |

Signature of the Co-Investigator.

Date:

Place:

*List of Enclosures:*

**10. Review Procedures:**

a. The meeting of the IEC shall be held at least once in each academic year. Additional meetings may convened as and when necessary.
b. The proposals will be sent to members at least one week in advance.
c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
d. Researchers will be invited to offer clarifications.
e. Independent Consultants/Experts may be invited to offer their opinion on specific research proposals.
f. The decisions will be minuted and Chairperson's approval taken in writing.

11. **Element of Review:** The IEC will review the following while considering the application:

a. Scientific design and conduct of the study.
b. Predictable risks/harms.
c. Potential benefits.
d. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
e. Management of research related injuries, adverse events, if any.
f. Compensation provisions, if needed.
g. Justification for placebo in control group, if any.
h. Availability of products after the study, if applicable.
i. Human participant information sheet and informed consent form.
j. Protection of privacy and confidentiality.
k. Involvement of the community, wherever necessary.
l. Adherence to all regulatory requirements and applicable guidelines
m. Competence of investigators, research and supporting staff
n. Facilities and infrastructure at study sites
o. Criteria for withdrawal of human participants, suspending or terminating the study.

**12. Expedited Review:**

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of sub-committee constituted by the Chairperson to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review may be decided by the IEC.

## 13. Decision-making:

a. Members will discuss the various issues before arriving at a consensus decision.
b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the Chairperson prior to the review of the application and recorded in the minutes.
c. Decisions will be made only in meetings where quorum is complete.
d. The expert consultants will only offer their opinions, and will have no voting rights.
e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
f. The procedure for having the application re-reviewed should be specified.
g. Modified proposals may be reviewed by an expedited review through a sub-committee as suggested earlier.
h. The Chairperson shall have authority to consider appeal by the applicants.

## 14. Communicating the decision

a. Decision will be communicated by the Member-Secretary.
b. Suggestions for modifications, if any, should be sent by Member-Secretary. .
c. Reasons for rejection should be informed to the applicants by Member-Secretary.
d. The schedule / plan of ongoing review by the IEC should be communicated to the PI by Member-Secretary.

## 15. Follow-up Procedures:

a. Interim report on the progress of the project should be submitted periodically as specified by the IEC.
b. A brief Final report should be submitted at the end of study.
c. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated.
d. Proposed protocol deviation, if any, should be informed in advance with adequate justifications for approval.
e. Premature termination of study should be notified with reasons along with summary of the data obtained so far to the IEC.
f. Proposed change of investigators / sites should be informed in advance to the IEC for approval.

## 16. Record keeping and Archiving

a. Curriculum- Vitae (CV) of all members of IEC.
b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
c. Minutes of all meetings duly signed by the Chairperson.
d. Copies of all existing relevant national guidelines on research ethics and laws along with amendments.
e. Copies of all correspondence with members, applicants and other regulatory bodies.

f. Interim and final reports of the approved projects.
g. All documents should be archived for at least five years after submission of final reports of the projects.

**17. Updating knowledge of the IEC members:**

a. All relevant new guidelines should be brought to the attention of the members.
b. Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.