North-Eastern Hill University

Institutional Ethics Committee of Human Samples and Participants (IECHSP)

IECHSP follows ICMR guidelines for conducting and supporting any research involving human participants. The committee can review the proposals submitted in accordance with the following guidelines.

1. Application procedure:

a. All proposals should be submitted in the prescribed application form, the details of which are given under documentation, along with a PDF copy by e-mail: memberscretaryiechsp@nehu.ac.in, to the Member-Secretary, IECHSP.

b. All the relevant documents should be enclosed with the application form in **3 copies**.

c. **Three copies** of the proposal, along with the application and documents in the prescribed format, duly signed by the Principal Investigator (PI) and Co-investigators/Collaborators, should be forwarded by the Head of the concerned Department before submitting to the ethical committee.

d. The date of the meeting will be intimated to the PI to be present and to offer any clarification. A PowerPoint presentation should be prepared according to the following instructions.

- A presentation of 10 minutes (PPT 7-8 slides only) detailing the Title, Introduction and Background, Objectives, Methodology/ Protocol of the proposal, Ethics involved in the work, Inclusion-exclusion criteria, and Informed consent.

e. The decision will be communicated in writing. If a revision is to be made, the revised document should be **submitted within the two weeks** specified in the communication to obtain a clearance certificate.

2. Guidelines

For a thorough and complete review, all research proposals should be submitted with the following documents:

1. Name of the applicant with designation.
2. Name of the institute /Hospital/Field area where research will be conducted.
3. Approval of the Head of the Department.
4. Protocol of the proposed research.
5. Ethical issues in the study and plans to address these issues.
6. Ethical approval of the project was obtained from the hospital's human ethics committee, from which the samples were procured.

7. Proposal should be submitted with all relevant enclosure proformas, case report forms, questionnaires, follow-up cards, etc.

8. Informed consent process, including patient/ participant information sheet and informed consent form in local language(s) or the language that the participant is comfortable with. Minor modifications to the general format of this document may be made to meet the requirements of the research proposal.

9. Curriculum vitae of all the investigators with relevant publications in the last five years.

10. Any regulatory clearance required.

11. Source of funding and financial requirements for the project.

12. An agreement to report only Serious Adverse Events (SAEs) to IECHSP.

13. Statement of conflicts of interest, if any.

14. Agreement to comply with the relevant national and applicable international guidelines.

15. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangement for indemnity, if applicable (in study-related injuries);

16. Plans for publication of results, positive or negative, while maintaining the privacy and confidentiality of the study participants.

17. Any other information relevant to the study.

3. Review procedures:

a. The meeting of the IECHSP will be held **twice** a year, or additional meetings may be called depending on the number of proposals received. The proposals will be sent to members **at least 7 days in advance** by email.

b. Decisions will be taken by consensus after discussions in the meeting.

c. Researchers will be invited to give a presentation and offer clarifications.

d. Independent consultants/experts will be invited to offer their opinion on specific research proposals if needed.

e. The decisions will be recorded in minutes and the chairperson's approval taken in writing.

4. Elements of review

1. Academic and/or Scientific design and conduct of the study.

2. Approval of appropriate scientific review committees.

3. Examination of predictable risks/harms.

4. Examination of potential benefits.

5. Procedure for selection of subjects in methodology, including inclusion/exclusion, withdrawal criteria, and other issues like advertisement details.

6. Management of research-related injuries and adverse events.
7. Compensation provisions.
8. Patient information sheets and informed consent form in the local language.
9. Protection of privacy and confidentiality.
10. Involvement of the community, wherever necessary.
11. Plans for data analysis and reporting.
12. Adherence to all regulatory requirements and applicable guidelines.
13. Competence of investigators, research, and supporting staff.
14. Facilities and infrastructure of study sites.
15. Criteria for withdrawal of participants, suspending or terminating the study.