



NEIGRIHMS

NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCE
(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)

INSTITUTION ETHIC'S COMMITTEE

Chairman:

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Principal, NEIGRIHMS
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NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCE
(An Autonomous Institute, Ministry of Health and Family Welfare, Government of India)



INSTITUTION ETHIC'S COMMITTEE, NEIGRIHMS (IEC)

Operating Manual (OM)

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P. O. NEIGRIHMS

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3rd Institutional Ethics Committee (IEC), NEIGRIHMS, Shillong

Constituted by: Prof. (Dr.) A G. Ahangar, Director, NEIGRIHMS

- | | |
|--|-------------------------|
| 1. Prof. F.U. Ahmed
Ex-Director, NEIGRIHMS,
Director, Integral Institute of Medical Science Research, Lucknow, UP | Chairman |
| 2. Dr. A. Dkhar,
DHS, (MI), Govt. of Meghalaya, Shillong | Member |
| 3. Prof. A.K. Nongkynrih
Prof. Sociology, NEHU, Shillong. | Member |
| 4. Mr. Emerald Warjri
Retd. Judge
Law and Parliamentary Affairs, Govt. of Meghalaya | Member |
| 5. Prof. Vandana Raphael
Dean, NEIGRIHMS & HOD Pathology | Member |
| 6. Dr. Md. Yunus
Additional Prof., Anaesthesiology & Co-ordinator of Medical Education Unit, NEIGRIHMS | Member |
| 7. Dr. M.K. Saikia
Associate Prof, CTVS, NEIGRIHMS | Member |
| 8. Dr. A.K. Ropmay
Associate Prof. Forensic Medicine, NEIGRIHMS | Member |
| 9. Prof. A. Santa Singh
Principal, NEIGRIHMS & HOD Dept. of Obs & Gynae | Member Secretary |

1. Preamble:

North – Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS) is an autonomous institute under the Ministry of Health and Family Welfare established for medical education, research, and patient care especially in the north – eastern India. One of the mandates of the NEIGRIHMS is to conduct research in various branches of medical sciences involving human beings. The involvement of the human beings raises issues of ethics in research. Institutional Ethics Committee is required to be constituted in every such institute to ensure the ethical practices by the researchers.

2. Objectives of the IEC:

- a) To protect the dignity, rights and the well being of the potential research participants.

- b) To ensure that the universal ethical values and the international scientific standards are expressed in terms of the values and the customs of the communities in the north - eastern region.

- c) To assist in the development, education, and the training of a research community responsive to the health care requirements of the communities in the north – eastern region in particular and wider communities in general.

- d) Further, the objective of this OM is to contribute to the effective functioning of the Institutional Ethics Committee (IEC) so that a quality and consistent ethical review mechanism for health and Biomedical research is put in place for all proposals dealt by the Committee as prescribed by the Ethical guidelines of concerned national agencies for biomedical teaching, research and other related activity (wherever applicable) involving the use of and participation of human samples / participants.

3. Role of IEC:

- a. To review and approve all types of research proposals involving human samples / participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants.

b. To ensure that the goals of research, however important, are not permitted to override the health and well-being of the research subjects by advising the researchers on all aspects of the welfare and safety of the research participants.

c. To oversee that all the cardinal principles of research ethics *viz.*, autonomy, beneficence, non-maleficence 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, *e.g.*, annual reports, final reports and other required steps. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

d. To ensure the scientific soundness and technical excellence of the proposed research through appropriate scientific review of all research projects involving human samples / participants to be conducted in the NEIGRIHMS, irrespective of the funding agency.

e. To inform all the members of any changes in the regulatory requirements in the matters of medical ethics in research and its standards

f. To keep the members informed of the latest national and international developments regarding medical ethics

4. Modification / Amendments in the role and functioning of IEC:

The role of IEC can be modified / amended, as and when necessary, in conformity with national guidelines.

5. Composition of IEC:

The composition of the IEC, as an independent and competent body, shall be as follows:

a. Chairperson (not an employee of NEIGRIHMS)

b. Deputy Chairperson

c. Member - Secretary (an employee of NEIGRIHMS)

d. Clinician (an employee of NEIGRIHMS)

e. Clinician (not an employee of NEIGRIHMS)

f. Basic Medical Scientist (not an employee of NEIGRIHMS)

- g. Basic Medical Scientist (an employee of NEIGRIHMS)
- h. Legal Expert
- i. Social Scientist / Representative of NGO / Community Leader

The IEC can invite subject experts and community leaders if required given the specific nature of the individual research projects.

6. Authority under which IEC is constituted:

The Director, NEIGRIHMS shall constitute the IEC in accordance with the OM.

7. Membership:

- a. The duration of appointment of each member shall be for a period of 3 years
- b. A member can be replaced in the event of death, 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 categorically by the members to the IEC in writing to the chairperson before the date of the meeting.

8. Quorum requirements:

A minimum of two-thirds of the total members is required as a quorum to hold a meeting of the IEC. All decisions shall be taken in the meetings of the IEC and not by circulation of project proposals to the individual members.

9. Offices:

The Chairperson or her/his nominee will conduct all the 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.

10. Application Procedures:

- a. All applications, submitted in the prescribed form (12 copies), should be addressed to the chairperson, IEC.

- b. Photocopies of all the relevant documents (only one copy of 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-investigator(s) / Collaborator(s) should be forwarded by the Head of the Department 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 decisions 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 to the IEC within a stipulated period of time as specified in the communication.

11. Prescribed Application Form for Clearance of Research Project by IEC :

- a. Name of the Investigator/co-investigator with designation :
- b. Name of the Department where research will be conducted :
- c. Protocol of the proposed research involving human samples / participants*:
- d. Ethical issues in the study and plans to address these issues :
- e. Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards, etc.:
- f. Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language /English / Hindi :
- g. For any drug / device trial, all relevant publications / pre-clinical data and clinical trial data from other institutions within the country / other countries, if available :
- h. Curriculum Vitae of all the investigators with relevant publications during the last five years :
- i. Regulatory clearances (other than IEC, NEIGRIHMS), if required :
- j. Details of Funding agency/sponsors and fund allocation for the proposed work.
- k. An agreement to report only Serious Adverse Events (SAE) to IEC:
- l. Statement of conflicts of interest, if any:
- m. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, 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:
- n. Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants:
- o. Agreement to comply with the relevant national guidelines for research in human genetic, transplantation etc, as and when applicable.
- p. Any other information relevant to the study:

Signature of Principal Investigator (PI)

Place:

Date:

Signature of Co-investigator(s)

Place:

Date:

* The protocols should include among other things the following:

- a. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
- b. Subject recruitment procedures.
- c. Inclusion and exclusion criteria for entry of subjects in the study.
- d. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedure, if any.
- e. A description of plans to withdraw or withhold standard therapies in the course of research.
- f. The plans for statistical analysis of the study.
- g. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
- h. Storage and maintenance of all data collected during the trial.
- i. Agreement to comply with national and international GCP protocols for clinical trials.

12. Review Procedures:

- a. The meeting of the IEC should be held at least two times in one academic calendar. Additional meetings may be 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.
- d. Researchers may 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 recorded and Chairperson's approval taken in writing

13. Elements of Review :

The IEC (NEIGRIHMS) will review the following while considering the application:-

- a. Scientific design and conduct of the study
- b. Examination of predictable risks / harms
- c. Examination of potential benefits
- d. Procedure for selection of subjects in methodology including inclusion / exclusion, withdrawal criteria and other issues like advertisement details for the subject recruitment (wherever necessary)
- 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. Patient 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 patients, suspending or terminating the study

14. Expedited review:

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of a Subcommittee 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.

15. Decision – making:

- a. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- 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

- c. Decisions will be made only in meetings where quorum is complete.
- d. The expert consultants will only offer their opinions, and shall not take part in the decision making process.
- e. the procedure for having the application re-reviewed should be specified.
- f. Modified proposals may be reviewed by an expedited review through a Subcommittee as suggested earlier.
- g. The Chairperson shall have authority to consider appeal by the applicants.

16. Communicating the decision:

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

17. 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 the study.
- c. All Serious Adverse Events (SAEs) and the interventions undertaken should be intimated.
- d. Protocol deviation, if any, should be informed 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. Any proposed change of investigators / sites should be informed to the IEC in advance for approval.

18. 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. Copy of all existing relevant national guidelines on research ethics and laws along with amendments.
- e. Copy of all correspondence with members, applicants and other regulatory bodies.
- f. Interim, Reports and Final report of the approved projects.

g. All documents related to the projects should be archived for at least five years after submission of the Final Report.

Appendix – I

1st Institutional Ethics Committee (IEC), NEIGRIHMS, Shillong.

Constituted by : Prof. (Dr.) R. K. Sarma, Director, NEIGRIHMS

Members :-

1. Prof. Lalthantluanga, H.O.D., Biochemistry, NEHU, Shillong – Chairperson
2. Dr. K. H. Lakiang, DHS (MI), Meghalaya , Shillong – Co-Chairperson
3. Prof. Nikhlesh Kumar, H.O.D., Sociology, NEHU, Shillong – Member
4. Dr. Andreas Dkhar, Medicine Specialist, Civil Hospital, Shillong – Member
5. Mr. Mr. B. Lamare, Rtd. Justice, Gauhati High Court, Shillong – Member
6. Dr. A.C.Phukan, Associate Professor, Microbiology, NEIGRIHMS, Shillong – Member
7. Dr. Rashna Dass, Assistant Professor, Paediatrics, NEIGRIHMS, Shillong – Member
8. Dr. V. Raphael, Associate Professor, Pathology, NEIGRIHMS, Shillong – Member Secretary

Appendix – II

2nd Institutional Ethics Committee (IEC), NEIGRIHMS, Shillong.

Constituted by : Prof. (Dr.) M. E. Yeolekar, Director, NEIGRIHMS

Members :-

1. Dr. A. K. Barooah, Ex- Director, NEIGRIHMS, Guwahati, Assam – Chairperson.
2. Dr. A. S. Kynjing, DHS, Govt. of Meghalaya , Shillong – Co-Chairperson.
3. Dr. P. Gangadhar Rao, Director, NEIST, Jorhat, Assam – Member
4. Mr. B. Lamare, Rtd. Justice, Gauhati High Court, Shillong – Member
5. Shri Mendon Pariat, Head Man, Umpling, Shillong – Member
6. Prof. (Dr.) Ashima Bhattacharyya, HOD, Anatomy, NEIGRIHMS, Shillong – Member
7. Prof. (Dr.) Noor Topno, HOD, General Surgery, NEIGRIHMS, Shillong – Member
8. Dr. Juditha Syiemlieh, Radiotherapist, Civil Hospital, Shillong – Member
9. Prof. (Dr.) A. C. Phukan, HOD, Microbiology, NEIGRIHMS, Shillong – Member Secretary.

Appendix – III

3rd Institutional Ethics Committee (IEC), NEIGRIHMS, Shillong

Constituted by: **Prof. (Dr.) A G. Ahangar**, Director, NEIGRIHMS

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|--|-------------------------|
| 10. Prof. F.U. Ahmed | Chairman |
| Ex-Director, NEIGRIHMS,
Director, Integral Institute of Medical Science Research, Lucknow, UP | |
| 11. Dr. A. Dkhar, | Member |
| DHS, (MI), Govt. of Meghalaya, Shillong | |
| 12. Prof. A.K. Nongkynrih | Member |
| Prof. Sociology, NEHU, Shillong. | |
| 13. Mr. Emerald Warjri | Member |
| Retd. Judge
Law and Parliamentary Affairs, Govt. of Meghalaya | |
| 14. Prof. Vandana Raphael | Member |
| Dean, NEIGRIHMS & HOD Pathology | |
| 15. Dr. Md. Yunus | Member |
| Additional Prof., Anaesthesiology & Co-ordinator of Medical Education Unit, NEIGRIHMS | |
| 16. Dr. M.K. Saikia | Member |
| Associate Prof, CTVS, NEIGRIHMS | |
| 17. Dr. A.K. Ropmay | Member |
| Associate Prof. Forensic Medicine, NEIGRIHMS | |
| 18. Prof. A. Santa Singh | Member Secretary |
| Principal, NEIGRIHMS & HOD Dept. of Obs & Gynae | |