Standard Operating Procedure (SOP)

Institute Ethics Committee of

National Institute of Technology Meghalaya

(Institute of National Importance)

(IEC-NITM)

1. Authority under which IEC constituted:

The National Institute of Technology (NIT) Meghalaya is one among the thirty NITs in India established under the NIT Act 2007 (Amended 2012) of the Parliament of India as Institutes of National Importance with full funding support from the Ministry of Education, Government of India. The Institute has a significant contribution to the world of knowledge and technology and to the development of the state, the region, and the nation. The objectives of the Institute ethics committee (IEC-NITM) is to ensure an ethical review of all the research proposals related to health and biomedical research involving human participants in accordance with the ICMR guidelines. The committee will also take care of the ethical practices to be followed by the researchers of the Institute. The Institute will comply all the regulation of CDSCO (DCGI), Drugs and Cosmetic Act 1945, New Drugs and Clinical Trials Rules 2019, and other regulation of ICMR.

The Director of NIT Meghalaya will constitute the IEC-NITM to facilitate research involving human subjects as per guidelines set by the ICMR in accordance with the SOP.

2. Membership requirements of the Ethics Committee:

The Institute Ethics committee should be multidisciplinary and multi-sectoral to safeguard the interests and welfare of all sections of the community and society. The number of members in the IEC should preferably be between 7 and 15, and a minimum of five members should be present to meet the quorum requirements. The IEC should have a balance between medical and non-medical members/technical and non-technical members. If required, subject experts may be invited to seek opinions.

The Institute Ethics committee will be constituted with the following members. The Director of the Institute will appoint the members.

(i) Chairperson - an expert from outside the Institute.
(ii) Member Secretary – One faculty from the Institute.
(iii) Medical Scientists from outside of the Institute - 01 or more member.
(iv) Clinician from outside the Institute - 01 or more member.
(v) Non Medical Scientific Member – 01 or more member
(vi) Legal expert from outside of the Institute - 01 member.
(vii) Non-Medical: Social Scientist/ philosopher/ethicist/theologian from outside of the Institute - 01 member.
(viii) Lay person from outside of the Institute - 01 member.

The presence of at least one woman in the committee is mandatory.

3. The terms of reference of the committee:

Chairperson: The Chairperson of the committee shall be from outside of the Institute and will be appointed by the Director of the Institute. The Chairperson will be responsible for conducting all committee meetings and will preside over in the committee's functions. In an emergency situation, the Chairman can nominate a Committee Member as an acting Chairperson preferably from outside of the Institute, to avoid conflict of interest. The acting Chairperson will have all the powers of the Chairperson for the respective meeting.

Member Secretary: The Member Secretary of the IEC-NITM will be a faculty member of the Institute and will be nominated by the Director. The Member Secretary will be responsible for the followings.

(i) To schedule and organize IEC meetings in consultation with the Chairperson

(ii) To prepare the agenda for meetings and to circulate among the IEC members.

(iii) To prepare minutes of the meetings.

(iv) To accept research proposals and do the initial review for proper format and related documents.

(v) To circulate all the documents to be reviewed to the committee members.

(vi) To invite experts from the relevant area if it is required.

(vii) To notify the outcome of the review committee meeting to the Principal Investigator of research proposals.

(viii) To arrange for the training of IEC members.

(ix) To provide updates on relevant and contemporary guidelines to the committee members from time to time.

(x) To prepare, revision, and distribution of SOPs.

(xi) To perform other duties assigned by the Chairperson.

Responsibilities of IEC members:

(i) To attend IEC meetings regularly and actively participate in discussions and to take appropriate decisions.

(ii) To review, discuss research proposals submitted for evaluation.

(iii) To monitor any serious adverse event reports and recommend appropriate measures.

(iv) To review the progress reports and monitor ongoing studies.

(v) To provide information and documents related to training obtained in biomedical ethics and biomedical research.

(vi) To maintain the confidentiality of the documents of IEC meetings.

(vii) To declare conflict of interest, if any.

(viii) To suggest any changes that may be necessary for the SOPs of the IEC.

4. Conditions of appointment and the quorum required:

Membership requirements:

(i) The IEC members, including the Chairperson, Member Secretary, will be selected by the Director of the Institute considering their expertise, research interests, and experience.

(ii) Members can suggest the names of potential new members, but the final decision will remain with the Director.

(iii) The members should be willing to reveal his / her profession, affiliation; all reimbursement for the expenses related to the committee works. These details will be made available to the appropriate authority upon request.

(iv) The selected members should show commitment and willingness to dedicate necessary time and effort for the IEC works.

(v) The members should abide by the requirements laid in the SOP.

(vi) The members will be required to sign a confidentiality agreement at the start of their term regarding IEC meetings, applications, information on research participants, and related matters.

(vi) Non-institutional committee members will be paid an honorarium for each meeting.

The duration of the appointment will be initially for 3 years. At the end of 3 years, the committee is to be reconstituted, and new members will replace 50% of the members.

Quorum Requirements: A minimum of five members must be present in a meeting beside the Member Secretary and the Chairperson in order to issue valid advice and/or decision. The quorum must include at least one non-scientific member that may either be a lawyer, philosopher or a lay person or community member. In case of drug trials, the quorum should have at least one representative from basic medical scientist (preferably pharmacologist) and a clinician. No meeting will be considered valid if the quorum is not reached.

5. Procedure for resignation, replacement, or removal of members:

A member may be relieved or terminated of his/her membership in case of

(i) If a member resigns from the committee of his/her own.

(ii) If a member is not capable of performing his / her duty as a committee member.

(iii) In case of demise of a member.

Members may resign before completing their terms in writing to the Director and Chairperson, at least one month in advance prior to the next scheduled meeting. In case of resignation, the Director may appoint a new member and the appointment can be made with consultation with the Chairperson.

6. Details of members of ethics committee. The Director of NIT Meghalaya has constituted the ethics committee (IEC-NITM) on 15-10-2020 (Office order no. NITMGH/ES/CMMTE/2020-21/673 dated 15-10-2020).

Sl. No.	Name	To function as	Designation
1.	Prof. Kripamoy Aguan	Chairperson	Prof. Biotechnology & Bioinformatics, NEHU
2.	Dr. Naba Kamal Nath	Member	Asst. Prof., Dept. of Chemistry, NIT Meghalaya
3.	Dr. Kishore Debnath	Member	Asst. Prof., Dept. of Mechanical Engg., NIT Meghalaya
4.	Dr. Arpita Nath	Member	Asst. Prof., Dept. of Physics, NIT Meghalaya
5.	Dr. Saibadaiahun Nongrum	Member	Asst. Prof., Dept. of Biotechnology and Biochemistry, St. Anthony's College
6.	Dr. Nitesh Mozika	Member (Legal Expert)	Senior Advocate, High Court of Meghalaya
7.	Dr. Rajinder Singh Bawa	Member	Medical Officer NITM (Part time)
8.	Dr. Henry Nongrum	Member	Medical Scientist
9.	Mr. Shanakar Pandey	Member	Social Worker
10.	Mr. Wanroy Challam	Member	The Headman of the locality and Community Representative
11.	Dr. Gitish Kishor Dutta	Member Secretary	Associate Professor, Dean(R&C), NIT Meghalaya

7. The standard operating procedures to be followed by the committee in general:

(i) The meeting of the ethics committee will be held with an interval of six months or upon receiving a proposal, whichever applicable, in consultation with the Chairperson and members of IEC-NITM depending on the research proposals received.

(ii) The applicant or the project investigator may be invited to make a presentation on the proposal or elaborate on specific issues.

(iii) The members will be given 15 days' time in advance to review research proposals and the relevant documents.

(iv) The IEC will evaluate the possible risks to the subject with proper justifications, the expected benefits, and the adequacy of documentation to ensure privacy and confidentiality.

(v) Decisions will be taken only after reviewing a complete application with all the required documents necessary for the proposal.

(vi) The Member Secretary will prepare the minutes of the IEC meetings and then get it approved by all members of the committee before communicating to the Investigator or applicant.
(vii) Members having any conflict of interest will report to the Chairperson prior to the review of the application.

8. Policy on the protection of vulnerable population:

The proposals involving the subjects of the vulnerable population require adequate justification, and the IEC-NITM will give special consideration to protect the right and welfare of vulnerable subjects. The vulnerable subjects will be defined as per the standard guidelines of ICMR National Ethical Guidelines 2017. Potentially vulnerable groups may include children, prisoners, pregnant women, differently-abled persons, refugees, displaced persons, and economically or educationally backward persons. The committee will follow all the regulation and guidelines in reviewing the research that involves a vulnerable population as research subjects.

9. Training of Members:
(i) All the new relevant information on ethics will be brought to the attention of the members of IEC-NITM, by the Member Secretary.
(ii) The members will be encouraged to attend training programs/workshops/conferences in the field of research ethics for maintaining quality in ethical review.

10. Conflict of Interest Policy:
If a member has conflict of interest involving a project, the member should inform the Chairperson immediately and shall not participate in the proposal review or approval process except to provide any information requested by the Committee.
If an applicant submitting a proposal believes that an IEC-NITM member has a potential conflict, the applicant may request that the member be excluded from the review of the proposal. The request must be in writing and addressed to the Chairperson with proper justification and evidence.

11 . Submission process of research proposals:
All the research proposals (five hard copies and soft copy) should be submitted to the Member Secretary at least 3 weeks in advance with the following documents:
(i) An application in a prescribed format (Annexure I) along with a study protocol for the review of the IEC.
(ii) Curriculum vitae of all the investigators (PI and Co-PI) with relevant publications in the last five years.

(iii) Every application has to be routed through the concerned Head of the Department to the IEC.

(iv) A forwarding letter by the Head of the Institution / Head of the Department where research will be conducted.

(v) The protocol of the proposed research should at least include the following points:

(1) Objectives.

(2) Rationale for undertaking the investigations in human participants.

(3) Inclusion and exclusion criteria for entry of participants.

(4) Methodology (including sample size, type of study design) etc.

(vi) List of ethical issues in the study and plans to address these issues.

(vii) The proposal should be submitted with all relevant enclosures such as:

(1) Proformae.

(2) Case report forms

(3) Questionnaires

(4) Follow-up cards

(5) Participant recruitment procedures etc.

(6) Informed consent process, including patient information sheet and informed consent form in English, or Hindi or in local language(s).

(7) Investigator's brochure for trial on drugs/devices/medical implants/vaccines/ herbal remedies and statement of relevant regulatory clearances.

(8) For any trial for drugs/devices/medical implants/vaccines/ herbal remedies, all relevant pre-clinical animal data and clinical trial data from other centres at the national and international level, if available.

(9) Any necessary regulatory clearances.

(10) Finance related documents such as the source of funding, financial requirements for the project, and other financial issues, including those related to insurance.

(11) An agreement to report all Serious Adverse events (SAEs)

(12) Statement of Conflict of interests, if any.

(13) An agreement to comply with all national and international guidelines.

(14) 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 indemnity arrangements, if applicable (in study-related adverse events, injury, discomfort); a description of the arrangements for insurance coverage for research participants, if applicable.

(15) All significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other IECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

(16) Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the participants.

(17) Any other information relevant to the study.

12 . Review procedures:

(i) The IEC Meeting will be conducted after receiving a proposal from the applicant/Investigator or in an interval of 6 months, whichever applicable.

(ii) The proposals will be sent to members at least 15 days in advance.

(iii) Decisions will be taken only after achieving a general agreement after discussions, and whenever needed, voting will be done.

(iv) If needed, researchers (PI and/or co-PI) will be invited to offer presentation/clarifications.

(v) If needed, independent consultants/Experts will be invited to offer their opinion on specific research proposals.

(vi) The decisions will be minuted, and Chairperson's approval will be taken in writing.

13. Element of the review

(i) Scientific design and conduct of the study.

(ii) Approval of appropriate scientific review committees.

(iii) Examination of predictable risks/harms.

(iv) Examination of potential benefits.

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

(vi) Management of research related injuries, adverse events.

(vii) Compensation provisions.

(viii) Justification for placebo in the control arm, if any.

(ix) Availability of products after the study, if applicable.

(x) Patient information sheet and informed consent form in the local language.

(xi) Protection of privacy and confidentiality.

(xii) Involvement of the community, wherever necessary.

(xiii) Plans for data analysis and reporting.

(xiv) Adherence to all regulatory requirements and applicable guidelines

(xv) Competence of investigators, research, and supporting staff.

(xvi) Facilities and infrastructure of study sites.

(xvii) Criteria for withdrawal of patients, suspending or terminating the study

14. Procedure for expedited review:

The proposals with no or minimal risk to the trial participants may be subjected to expedited review. Expedited review may also be taken up in the following cases.

(1) Re-examination of a proposal already examined by the IEC.

(2) Similar study proposal for which IEC had already given approvals earlier.

(3) Study of minor nature

(4) An urgent proposal of national interest having minimum risk.

All expedited approvals will be given in a meeting convened by the Chairperson with a quorum of at least 3 members of IEC. The decision taken by the committee on expedited approval will be brought to the notice of the main committee members for ratification. Only the Chairperson shall take the decision for an expedited review.

15. Decision-making

(i) The members will discuss the various issues before arriving at a consensus decision.

(ii) 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 before the review of the application and recorded in the minutes.

(iii) Decisions will be made only in meetings where a quorum is complete.

(iv) Only members can make the decision. The expert consultants will only offer their opinions.

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

(vi) In cases of conditional decisions, clear suggestions for revision, and the procedure for having the application re-reviewed should be specified.

(viii) Modified proposals may be reviewed by an expedited review through identified members.

(ix) Procedures for appeal by the researchers should be clearly defined.

16. Communicating the decision

(i) The decision will be communicated to the applicant by the Member Secretary in writing.

(ii) Suggestions for modifications, if any, should be sent by IEC

(iii) Reasons for rejection should be informed to the applicant (PI or Co-PI).

(iv) The schedule / plan of ongoing review by the IEC-NITM should be communicated to the PI and/or Co-PI.

17. Follow up procedures

(i) Reports should be submitted at annually for review.

(ii) The final report should be submitted at the end of the study.

(iii) Protocol deviation, if any, should be informed with adequate justifications.

(iv) Any amendment to the protocol should be resubmitted for renewed approval.

(v) Any new information related to the study should be communicated.

(vi) Premature termination of the study should be notified with reasons along with a summary of the data obtained so far.

(vii) Change of investigators / sites should be informed.

1. Record keeping and Archiving

(i) Curriculum Vitae (CV) of all members of IEC.

(ii) Copy of all study protocols with enclosed documents, progress reports, and Serious Adverse Events.

(iii) Minutes of all meetings duly signed by the Chairperson and all members.

(iv) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

(v) Copy of all correspondence with members, researchers, and other regulatory bodies.

(vi) Final report of the approved projects.

(vii) All the documents related to research proposals will be archived for a minimum period of 5 years in the Institute, following the completion of the study.

REFERENCES

(1) Ethics Committee guidelines of All India Institute of Medical Sciences, Bhubaneswar

(2) Institutional Ethics Committee NEIGRIHMS, Shillong

(3) Institute Ethics Committee IIT Delhi

(4) ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017

Annexure-I

APPLICATION FOR CLEARANCE OF PROJECT BY IEC

1.	Title of the project: _____
2.	Investigator(s) details: _____
3.	Co-investigator(s) details: _____
4.	Objectives of the study: _____ _____ _____
5.	Methodology (in brief): _____ _____ _____ _____ _____
6.	Details of funding agency and fund allocation: _____ _____
7.	Work on the project has started: ☐ Yes ☐ No
8.	Inclusion/exclusion criteria for human samples/participants: _____ _____
9.	Risks involve and safety measure(s): _____ _____
10.	A statement specifying to maintain confidentiality: _____ _____
11.	Conflict of Interest, if any:_____ _____
12.	Permission from Drug Controller General of India (DCGI): ☐ Required ☐ Not required ☐ Received ☐ Applied (Date):
13.	Clinical Trials Registry- India (CTRI) status, in case of clinical trials: _____
14.	Any other relevant information: _____ _____
15.	Participant information form (attached): ☐ Yes ☐ No
16.	Participant informed consent form (attached): ☐ Yes ☐ No

Annexure-II

Signature of the Applicant

PARTICIPANT INFORMATION FORM

1.	**Title of the project:** _____
2.	**Investigator(s) details:** _____ _____
3.	**Aims and methodology of the project:** _____ _____ _____ _____ _____
4.	**Details of funding agency and fund allocation:** _____
5.	**Expected duration of the subject participation:** _____
6.	**Benefits expected from the research to the subject or to others:** _____ _____ _____
7.	**Risks involve and safety measure(s):** _____ _____
8.	**A statement specifying to maintain confidentiality:** _____ _____
9.	**Provision of treatment of subject for research related injury:** _____ _____
10.	**Compensation to subject for disability or death from injury:** _____ _____
11.	**Freedom of subject to participate/withdraw from research:** _____
12.	**Any other relevant information:** _____ _____

Signature of the Applicant

Annexure-III

PARTICIPANT INFORMED CONSENT FORM

Project number:
Participant identification number for trial:
Title of the project:
Investigator(s) details:

I have carefully read/explained in detail to me the contents of the Participant Information Form (Dated: _____). The purpose of the research, benefits of the research, potential risks of the research, and other relevant information of the research have been explained to me in detail. I have fully understood the information provided in the form. I understand that that my participation is a requirement to conduct the research and I am free to withdraw at any time without giving any reason. The information about me for my participation in this research may be collected. I give my consent to take part in the research.

Participant:
Signature/Thumb Impression: _____
Name: _____
Son/Daughter/Spouse of: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

This is to certify that the consent has been given in my presence.

Principal Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Witness – 1:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Witness – 2:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Annexure-IV

UNDERTAKING

Date: _____

Annexure-I along with this undertaking is being submitted for the purpose of obtaining the ethical clearance to conduct the research. It is being stated that the project titled "_____ _____" requires _____ to conduct the research. The research will only be started after obtaining the clearance from the Institute Ethics Committee. The research will be performed following the regulatory guidelines. The research is being carried out by the Department/Centre _____at_____.

It is also being undertaken that the Participant Information Form has been translated into Hindi for the convenience of the participant(s).

Principal Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Co-Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Co-Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Co-Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____

Co-Investigator:
Signature: _____
Name: _____
Address: _____
Contact No. _____
Date: _____ Place:_____