COVER PAGE

STANDARD OPERATING PROCEDURES FOR "INSTITUTE ETHICS COMMITTEE"

NATIONAL INSTITUTE OF TECHNOLOGY MEGHALAYA

BIJNI COMPLEX,LAITUMKHRAH SHILLONG 793003

	Name	Designation	Signature	Date
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EFFECTIVE DATE: 12/11/2024

VALID TILL: 11/11/2026

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FORMS

1. PURPOSE

The Institute Ethics Committee (IEC-NITM) shall carry out the ethical review of the research proposals involving the use of human samples/participants in accordance with the ICMR and other regulatory guidelines and the SOP of the Institute Ethics Committee**.**

2. SCOPE AND RESPONSIBILITIES

2.1 Review research projects involving human subjects, including human biological materials and human biological data, regardless of the funding agency.

2.2 Ensure research and Institutional activities comply with relevant ethical guidelines, laws, regulations, and policies.

2.3 Investigate and address ethical issues or complaints related to research or Institutional activities.

2.4 Supervise the welfare and rights of human subjects involved in research, ensuring the safety and well-being of all individuals involved.

2.5 Evaluate the informed consent process, risk-benefit ratio, distribution of burdens and benefits, and provisions for appropriate compensations when necessary.

2.6 Monitor and review ongoing research activities to ensure compliance with ethical standards.

2.7 To provide training and guidance to researchers and staff on ethical practices and procedures.

2.8 Identify and manage any potential conflicts of interest that could affect research integrity.

3. DETAILED INSTRUCTIONS

3.1. The authority under which IEC-NITM constituted

The National Institute of Technology (NIT) Meghalaya is one among the thirty-one NITs in India established under the NIT Act 2007 (Amended 2012) of the Parliament of India as Institutes of National Importance with 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 objective 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 Institute will comply all the regulations of CDSCO (DCGI), Drugs and Cosmetic Act 1945, and other regulations of ICMR.

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

3.2. Membership requirements of the Institute 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 their opinions.

The Institute Ethics Committee will comprise 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 member from the Institute.

(iii) Medical Scientists from outside of the Institute - 01 or more members.

(iv) Clinician from outside the Institute - 01 or more members.

(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) Layperson from outside of the Institute - 01 member.

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

3.3. The terms of reference of the committee:

Chairperson: The Chairperson of the committee shall be from outside of the Institute and appointed by the Director of the Institute. The Chairperson will be responsible for conducting all committee meetings and will preside over the committee's functions. In an emergency situation, the Chairman can nominate a Committee Member as 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 nominated by the Director. The Member Secretary will be responsible for the following.

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

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

(iii) Prepare the 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) Invite experts from the relevant area if required.

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

(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, revise, and distribute SOPs.

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

***Responsibilities of IEC members**:*

(i) Attend IEC meetings regularly, actively participate in discussions, and make appropriate decisions.

(ii) To review and 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 from the IEC meetings.

(vii) To declare a 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

4.1. *Membership requirements*

(i) The IEC members, including the Chairperson and 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 their professional affiliation and 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 the necessary time and effort to the IEC works.

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

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

The duration of the appointment will initially be three (03) years. At the end of 3 years, the committee is to be reconstituted by the Director of the Institute. Members of the previous committee can also be included in the new committee.

4.2. 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. In case of resignation, the Director may appoint a new member, and the appointment can be made in consultation with the Chairperson.

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

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings.
- If the member is a regular defaulter and fails to attend more than 3 meetings without any valid reason.

The membership shall be reviewed by the committee, and if deemed necessary, the IEC may decide to terminate the membership and recommend it to the Director, NIT Meghalaya, by the Chairperson of the IEC for necessary action.

4.3. ***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 decisions. The quorum must include at least one non-scientific member, who may be a lawyer, philosopher, layperson, or community member. In the case of drug trials, the quorum should have at least one representative from the basic medical scientist (preferably a pharmacologist) and a clinician. No meeting will be considered valid if the quorum is not reached.

5. ADDRESS OF THE OFFICE OF INSTITUTE ETHICS COMMITTEE

National Institute of Technology Meghalaya
Admin Building, Saitsophen, Sohra,
East Khasi Hills, Meghalaya 793108

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

(i) The ethics committee meeting will be held as per requirement or upon receiving a proposal, whichever is 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 them 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.

7. Policy on the protection of vulnerable populations:

The proposals involving the subjects of the vulnerable population require adequate justification, and the IEC will give special consideration to protect the rights and welfare of vulnerable subjects. The vulnerable subjects will be defined as per the standard guidelines of ICMR National Ethical Guidelines. Potentially vulnerable groups may include children, prisoners, pregnant women, differently-abled persons, refugees, displaced persons, and economically or educationally backward persons. **Only the full committee will accord approval and do an initial and continuing review of proposals involving vulnerable populations.** The committee will include representation in the selected vulnerable populations and, if needed, additional experts to review and approve the proposed research involving vulnerable subjects. The documentation for the same will be maintained. The Committee will ensure that all the regulations and guidelines in

reviewing the research that involves a vulnerable population as research subjects are followed. **Any new study submission, including vulnerable groups as potential research participants, will be reviewed by the full board meeting and cannot be reviewed under expedited procedures.** However, any subsequent review of amendments and continuing review applications involving vulnerable groups as potential research participants can be reviewed by expedited review procedures.

7.1. Obligations/duties of stakeholders to protect vulnerable participants as per ICMR National Ethical Guidelines 2017

Researchers

•Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection.
• Justify the inclusion/exclusion of vulnerable populations in the study.
• Conflict of interest (COI) issues must be addressed.
• Have well-defined procedures (SOPs) to ensure a balanced benefit-risk ratio.
• Ensure that prospective participants are competent to give informed consent.
• Take consent of the LAR when a prospective participant lacks the capacity to consent.
• Respect dissent from the participant.
• Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.
•Research should be conducted within the purview of existing relevant guidelines/regulations

Ethics Committees

• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified.
• Ensure that COI do not increase harm or lessen benefits to the participants.
• Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.
• Suggest additional safeguards, such as more frequent review and monitoring, including site visits.
• Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.
• ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD.

Sponsors

• The sponsor, whether a government, an institution, or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety.
• The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC).
• The sponsor should ensure the protection of the participants and research team if the research is on sensitive topics.

8. 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 to maintain quality in ethical review.

9. Conflict of Interest Policy:

Suppose a member has a conflict of interest involving a project. In that case, 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.

10. Submission process of research proposals

All the research proposals (hard copies and soft copies) should be submitted to the Member Secretary at least 3 weeks in advance with the following documents:

(i) An application in a prescribed format (Application Form for Initial Review) 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.

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

(vi) 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 centers 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.

Project Investigators from other Institutions can utilize the services of the IEC-NITM. In case of collaboration with Institutions or research centers, there should be a memorandum of understanding (MoU) to safeguard the interests of the researcher and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

The Institute can charge a fee for the review of proposals, and there is no predetermined limit, and it can be an internal decision- based on running costs.

11. Review procedures:

(i) The IEC Meeting will be conducted after receiving a proposal from the applicant/Investigator or as per the requirement to review any ongoing study.

(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 presentations/clarifications.

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

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

12. 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 and 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.

13. 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.

14. Exemption from review:

Proposals that may be considered for exemption from ethics committee review are those with less minimal risk where there are no linked identifiers, like

- comparison of instructional techniques, curricula, or classroom management methods
- research conducted on data available in the public domain for systematic reviews or meta-analysis
- observation of public behavior, when information is recorded without any linked identifiers and disclosure, would not harm the interests of the observed person
- quality control and quality assurance audits in the institution

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.

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

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

(ix) Only the committee is empowered to approve ethical clearances

(x) All the approved project titles by the IEC will be displayed on the Institute website.

16. Communicating the decision

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

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

(iii) The reasons for rejection should be communicated 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 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 noted, along with reasons and a summary of the data obtained so far.

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

(viii) Applicant must inform the time of completion of the study and must send the final result summary to IEC.

18. Continous Monitoring

(vii) Any severe violation and deviation from the approved procedures and guidelines in the approved project will be liable for the withdrawal of IEC

(viii) Any deviation from the approved procedure and guidelines should be brought to the IEC for review and approval. During the reviewing period, the altered part of the project should not be executed.

(ix) Any serious adverse events, including deaths that occur to participants during the execution of the project, should be reported immediately to the committee, Institute, and funding agency.

(x) The committee will review and determine the plan of action as per ICMR and other regulatory guidelines.

19. 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.

20. Review & request for revision of the existing SOP

(i) Any member of the IEC or Investigator of NITM who notices any inconsistency or has any suggestion on how to improve a procedure should communicate through the Member Secretary/Chairman of the IEC.

(ii) If IEC agrees with the request, then the appropriate team will be designated by the Director NITM and Chairman of IEC, NITM, to proceed with the revision process. If the Committee disagrees, the Member Secretary will inform the person who made the request for the decision.

(iii) The Member Secretary will regularly prepare the amendment or addendum (if any) to the existing SOP to the approved discussion points in the IEC meetings.

(iv) The Member Secretary will review the SOP at least every two years, incorporate the addendum, and record the date of review in the SOP master file.

All grievances should be addressed to the Chairperson, IEC-NITM.

Guidelines to be followed

1. National Ethical Guidelines for Biomedical and Health Research Involving Human Subjects.

   https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf

2. New Drugs and Clinical Trials Rules, 2019.

   https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4OA==

3. National Guidelines for Biomedical Research Involving Children
   https://thsti.res.in/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf

4. Medical Device Rules, 2017
   https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

5. National Guidelines for Stem Cells Research
   https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf

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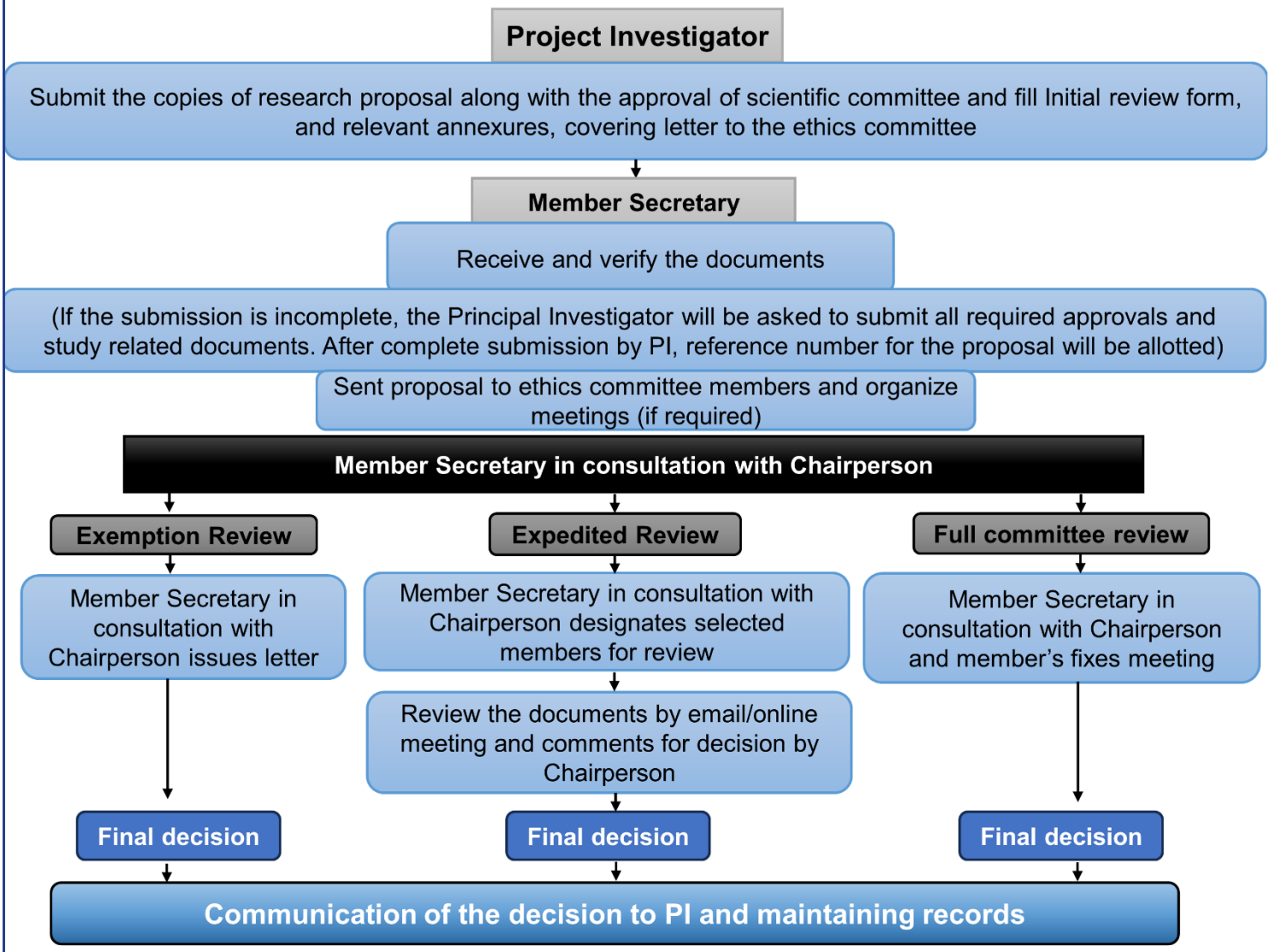
Project Investigator
Submit the copies of research proposal along with the approval of scientific committee and fill Initial review form, and relevant annexures, covering letter to the ethics committee
Member Secretary
Receive and verify the documents
(If the submission is incomplete, the Principal Investigator will be asked to submit all required approvals and study related documents. After complete submission by PI, reference number for the proposal will be allotted)
Sent proposal to ethics committee members and organize meetings (if required)
Member Secretary in consultation with Chairperson
Exemption Review
Expedited Review
Full committee review
Member Secretary in consultation with Chairperson issues letter
Member Secretary in consultation with Chairperson designates selected members for review
Member Secretary in consultation with Chairperson and member's fixes meeting
Review the documents by email/online meeting and comments for decision by Chairperson
Final decision
Final decision
Final decision
Communication of the decision to PI and maintaining records

ANNEXURES (FORMS)

Application Form for Initial Review

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

General Instructions: a) Tick one or more options as applicable.Mark NA if not applicable
b) Attach additional sheets, if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: .....(e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission

.....

ii) Co-Investigator at time of submission:

.....

(k) Duration of the study: .....

[1]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2]*Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

At site..... In India..... Globally .....

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

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SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

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.....r.....

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/	☐	Case Control	☐
Prospective	☐	Public Health	☐	Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples/ Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

.....

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site..... In India..... Globally .....

Control group..... Study group .....

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for saturation .....

.....

.....

.....

[3]*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.* *Version 2.0*

(b) Is there an external laboratory/outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

……

……

……

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* ……

Who will do the recruitment? ……

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)* ……

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs	☐	Pregnant or lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally ill (stigmatized or rare diseases)	☐		
Any other *(Specify)*:	☐		

iii. Provide justification for inclusion/exclusion ……

……

iv. Are there any additional safeguards to protect research participants?……

……

……

[4] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA / MoU*

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution?

If yes, Monetary ☐ Non-monetary ☐ *Provide details* Yes ☐ No ☐

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5] :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to item no. 8 Yes ☐ No ☐

.....

.....

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(b) Version number and date of Participant Information Sheet (PIS):.....

Version number and date of Informed Consent Form (ICF):.....

(c) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Witnessed consent ☐ Audio-Video (AV) consent ☐

Consent from LAR ☐ (If so, specify from whom) ..... For children<7 yrs ☐ parental/LAR consent Verbal assent from minor (7-12 yrs) along ☐ with parental consent Written assent from minor (13-18 yrs) along ☐ with parental consent

Other ☐

(specify) .....

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ (*Specify*) .....

Any tools to be used .....

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done .....

If translation has not been done, please justify .....

.....

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

.....

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/ Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/ Benefit sharing ☐
Right to withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ Identifying data ☐
Purpose and procedure ☐	Payment for participation ☐	Contact information of PI and Member ☐
Others(Specify) ☐		Secretary of EC

.....

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8] ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ N/A ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ N/A ☐

.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify.

Yes ☐ No ☐ N/A ☐

[7]*Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, Page 54 in Section 5.8.*

[8]*Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. *If Yes, specify* Yes ☐ No ☐ NA ☐

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐ If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) .....

.....

.....

.....

.....

(b)

Who will be maintaining the data pertaining to the study? ..... (c)

Where will the data be analyzed[9] and by whom? .....

(d) For how long will the data be stored? .....

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?.....

.....

.....

.....

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

.....

.....

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

.....

.....

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐ NA ☐

.....

.....

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐ NA ☐

.....

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

.....

.....

[9]*For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST [10]

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelinesfor Biomedical and Health Research Involving Human Participants and other applicable regulations and guide-lines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-I): 1. .... 2. ....
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherev-er applicable.

Name of PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Guide: .....

Signature: ..... dd mm yy

Name of HOD: .....

Signature: ..... dd mm yy

[10] *These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/ mm/yy	EC Remarks
18	CTRI	☐	☐	☐		
19	DCGI	☐	☐	☐		
20	HMSC	☐	☐	☐		
21	NAC-SCRT	☐	☐	☐		
22	ICSCR	☐	☐	☐		
23	RCGM	☐	☐	☐		
24	GEAC	☐	☐	☐		
25	BARC	☐	☐	☐		
26	Tribal Board	☐	☐	☐		
27	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28		☐	☐	☐		
29		☐	☐	☐		

**For multicentre research.*

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre

[11]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)* *Version 2.0*

(Annexure 1)

Application Form for Expedited Review

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No.* *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   - i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   - ii. Involves clinical documentation materials that are non-identifiable (data, documents, records). ☐
   - iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)). ☐
   - iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal. ☐
   - v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   - vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   - vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   - viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   - ix. Any other (please specify) .....

     .....
2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons[13] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

Version 2.0

(Annexure 2)

Application Form for Exemption from Review

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Choose reasons why exemption from ethics review is requested[14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): .....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

[14]*Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15]*Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

Version 2.0

(Annexure 3)

Continuing Review / Annual report format

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: Validity of approval:
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   dd mm yy dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....
   Number Completed:..... Number on followup:.....
   (b) Enrolment status – ongoing / completed/ stopped
   (c) Report of DSMB[16] Yes ☐ No ☐ NA☐
   (d) Any other remark.....
   .....
   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....
4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants? Yes ☐ No☐

   If yes, when / how: .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

Version 2.0

6. Is any new information available that changes the benefit - risk analysis of human participants involved in this study? Yes ☐ No ☐

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details: .....

.....

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's : ..... Type of SAE's: .....

.....

.....

(c) Is the SAE related to the study? Yes ☐ No ☐

Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

.....

.....

10. In case of multicenteric trials, have reports of off-site SAEs been submitted to the EC ? Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

.....

.....

Any other comments: .....

.....

Signature of PI: ..... dd mm yy

(Annexure 4)

Application/Notification form for Amendments

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD [18]

3. Impact on benefit-risk analysis Yes ☐ No ☐

If yes, describe in brief: .....

.....

4. Is any reconsent necessary? Yes ☐ No ☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

[18] *Location implies page number in the ICD/protocol where the amendment is proposed*

Version 2.0

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Date of EC approval dd mm yy Date of start of study dd mm yy
2. Participant ID:..... Date of occurrence dd mm yy
3. Total number of deviations /violations reported till date in the study: .....
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐
   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others *(specify)*	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-I: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

   If yes, give details.....

   .....

Signature of PI: ..... dd mm yy

Version 2.0

(Annexure 6)

Serious Adverse Event Reporting Format (Biomedical Health Research)

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight: .....(Kgs)
.....	.....	Male ☐ Female ☐	Height: .....(cms)
.....	.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE: dd mm yy

Date of reporting SAE: dd mm yy

Describe the event [19]:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE [20]

.....

.....

.....

.....

.....

5. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

.....

[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

   (Please list number of cases with details if available)

   .....

   .....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

   A. Expected event ☐ Unexpected event ☐

   B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

   .....

   In case of death, state probable cause of death.....

   C. No permanent/significant functional/cosmetic impairment ☐

   Permanent/significant functional/cosmetic impairment ☐

   Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

   .....

   .....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

    .....

11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

    .....

12. Provide any other relevant information that can facilitate assessment of the case such as medical history

    .....

    .....

13. Provide details about PI's final assessment of SAE relatedness to research.

    .....

    .....

    .....

Signature of PI: ..... dd mm yy

(Annexure 7)

Premature Termination/Suspension/ Discontinuation Report Format

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐
   Reason for Termination/Suspension/Discontinuation: .....

   .....

   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

   .....

   .....

   .....

5. Plans for post study follow up/withdrawal[21] (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures: .....

   Enrolled: ..... Consent Withdrawn: ..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI: ..... Reason(Give details): .....

   .....

[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Active on treatment: ..... Completed treatment : ..... Participants on follow-up: .....

Participants lost to follow up: ..... Any other: ..... Number of drop outs:.....

Reasons for each drop-out: .....

.....

.....

.....

7. Total number of SAEs reported till date in the study: .....

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No☐

If yes, provide details:.....

.....

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No☐

If yes, have you implemented that suggestion? Yes ☐ No☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐

(e.g., making arrangements for medical care of research participants): If Yes, provide details

.....

.....

Summary of results (if any): .....

.....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Version 2.0

(Annexure 8)

Application Form for Clinical Trials

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: ..... NABH accreditation number:..... EC registration number:.....

2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached ☐ Applied, under process ☐

   Not applied (State reason) ☐.....

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication or new route of administration	☐
Others (specify)	☐		

.....

4. Trial design of the study

I. Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(specify)*	☐	Equivalence trial	☐

.....

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

.....

.....

III. Describe the method of allocation concealment (blinding / masking), if applicable.

.....

..... *Version 2.0*

5. List the primary / secondary outcomes of the trial.

……

……

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any other agency such as public relation/human resource? Yes ☐ No ☐

If yes, Name and Contact details: ……

……

……

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(specify)*	☐

……

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; if yes, provide regulatory approval details. Yes ☐ No ☐ NA ☐

……

……

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details. Yes ☐ No ☐ NA ☐

……

……

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics.

……

……

IV. Provide details of patent of the drug/s, device/s and biologics.

……

……

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, provide details (100 words) ……

……

……

……

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22]……

……

……

10. Is there any anticipated incidence, frequency and duration of adverse events related to the intervention?

If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

……

……

……

11. Does the study use a placebo?

If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

……

……

……

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐

If no, please justify.

……

……

……

13. Are there any plans to withdraw standard therapy during the study? If yes, please justify. Yes ☐ No ☐ NA ☐

……

……

……

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify. Yes ☐ No ☐ NA ☐

……

……

……

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

……

……

……

[22] *In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐
(certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)

Other*(Specify)* ☐

……

List the languages in which translations were done ……

Justify if translation not done……

……

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

……

……

……

I. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration?

Please provide details. Yes ☐ No ☐

……

……

II. Is the PI trained in GCP in last 3 years? If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: …… dd mm yy

(Annexure 9)

Serious Adverse Event Reporting Format (Clinical trials)

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Participant details :

Initials and Case No./ Subject ID	Age at the time of event	Gender	
.....	.....	Male ☐	Weight:.....(Kgs)
.....		Female ☐	Height:..... (cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report dd mm yy

What was the assessment of relatedness to the trial in the initial report?

By PI – Related ☐ Unrelated ☐ By Sponsor – Related ☐ Unrelated ☐ By EC – Related ☐ Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:.....

.....

.....

4. Date of onset of SAE: dd mm yy Date of reporting: dd mm yy

5. Onset lag time after administration of intervention: ..... Location of SAE (Clinic/Ward/Home/Other) .....

6. Details of suspected study drug/device/investigational procedure causing SAE:

I. Suspect study drug (include generic name) device/intervention: .....

.....

II. Indication(s) for which suspect study drug was prescribed or tested: .....

.....

III. Route(s) of administration, daily dose and regimen, dosage form and strength : .....

.....

IV. Therapy start date: dd mm yy Stop date: dd mm yy

7. Was study intervention discontinued due to event? Yes ☐ No ☐

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8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure? Yes ☐ No ☐
If yes, provide details about the reduced dose.....

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.....

10. Concomitant drugs history and lab investigations:

I. Concomitant drug (s) and date of administration: dd mm yy

.....

.....

II. Relevant test/laboratory data with dates: dd mm yy

.....

.....

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc).....

.....

.....

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

.....

.....

12. Seriousness of the SAE:

Death	☐	Congenitial anomaly	☐
Life threatening	☐	Required intervention to prevent	
Hospitalization-initial or prolonged	☐	permanent impairment / damage	☐
Disability	☐	Others *(specify)*	☐

.....

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

.....

.....

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other *(specify)*	☐

.....

15. Was the research participant continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide details about PI's final assessment of SAE relatedness to trial.

.....

.....

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐
Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided / to be provided the participants (Include information on who pays, how much, and to whom).....

.....

Signature of PI: ..... dd mm yy *Version 2.0*

(Annexure 10)

Application Form for Human Genetics Testing Research

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Describe the nature of genetic testing research being conducted.
(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

.....

.....

.....

2. Does the study involve pretest and post-test counselling? If yes, please describe. Yes ☐ No ☐ NA ☐

.....

.....

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

.....

.....

.....

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐

If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

.....

.....

.....

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐

If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

.....

.....

6. What measures are taken to minimize/mitigate/eliminate conflict of interest?

.....

.....

7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐

If yes, has this been addressed in the informed consent ? Yes ☐ No ☐

Signature of PI: ..... dd | mm | yy

Version 2.0

(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Data collection method used in the study

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/Oral	☐
Others *(Specify)*	☐			history/Case studies	

.....

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

.....

.....

.....

2. Type of informed consent used in the study.

Individual consent ☐ Gate-keeper consent ☐ Community consent ☐

Others ☐ *(specify)*.....

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

.....

.....

.....

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

.....

.....

.....

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

.....

.....

.....*Version 2.0*

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

……

……

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……

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……

……

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

……

……

……

……

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

……

……

……

III. Describe how do societal benefits outweigh individual harm.

……

……

……

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

……

……

……

……

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

……

……

……

Signature of PI: …… dd mm yy

Version 2.0

(Annexure 12)

Study completion/Final report format

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. Provide details of:

a) Total number of study participants approved by the EC for recruitment: .....

b) Total number of study participants recruited: .....

c) Total number of participants withdrawn from the study (if any): .....

Provide the reasons for withdrawal of participants[23] : .....

.....

.....

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....

.....

.....

5. Describe the main ethical issues encountered in the study (if any) .....

.....

.....

.....

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
   Deviations: ..... Violation: ..... Amendments: .....
7. Describe in brief plans for archival of records / record retention:.....

.....

.....

.....

.....

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[23] *Explanation for the withdrawal of participants whether by self or by the PI*

8. Is there a plan for post study follow-up? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

.....

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No☐

If yes, describe in brief: .....

.....

.....

.....

11. Describe results (summary) with Conclusion [24] : .....

.....

.....

.....

.....

12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No☐

If yes, provide details.....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

(Annexure 13)

Format for Curriculum Vitae for Investigators

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

Name:
Present affiliation *(Job title, department, and organisation)*:
Address (Full work address):
Telephone number: Email address:
Qualifications:
Professional registration *(Name of body, registration number and date of registration):*
Previous and other affiliations *(Include previous affiliations in the last 5 years and other current affiliations):*

Projects undertaken in the last 5 years:

Relevant research training/experience in the area [25] :
Relevant publications *(Give references to all relevant publications in the last five years):*

Signature	Date:

[25] *Details of any relevant training in the design or conduct of research, for example in the Ethics Training, Human participants' protection courses, Clinical Trials Regulations, Good Clinical Practice, consent, research ethics training or other training appropriate to non-clinical research. Give the date of the training*

(Annexure 14)

Application Form for Project extension

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No. *(For office use):*

The project extension must be duly submitted no later than 30 days before the approval expires.

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1.	EC Reference No: _____	
2.	Date of EC Approval:	Duration of Approval months/ years
3.	Date of Start of study:	Date of Completion: *(As per the first approval granted)*
	Duration of Extension sought: months/ years	
	Period of Extension sought from	To
4.	Have there been any modifications in the budget for the extension sought? **If No, skip to item no.5** Yes ☐ No ☐ If yes, discuss in detail:	
5.	Does the study involve recruitment of participants? Yes ☐ No ☐ (a) If yes, Total number for study No. (b) Screened: No. Enrolled: No. (c) Number Completed: No. on followup: No. (d) Enrolment status – ongoing / completed/ stopped No. (e) If ongoing , Expected No. (f) Report of DSMB* Yes ☐ No ☐ NA ☐ ** In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.* (g) Any other remark	

	(h) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐ If yes, total number withdrawn and reasons:
6.	Have there been any amendments in the research protocol/informed consent document (ICD) for the extension sought? Yes ☐ No ☐ **If No, skip to item no.7**
	(a) If yes, discuss in detail:
	(b) In case of amendments in the research protocol/ICD, will re-consent be sought from participants? If yes, when / how: Yes ☐ No ☐

7. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes ☐ No ☐

   If yes, discuss in detail:

8. Have any ethical concerns occurred during the study? Yes ☐ No ☐

   If yes, give details

9. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

   Describe in brief:

   (b) Have any SAE's occurred since last review? Yes ☐ No ☐

   If yes, number of SAE's : Type of SAE's:

   (c) Is the SAE related to the study? Yes ☐ No ☐

   Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

10. Has there been any protocol deviations/violations that occurred during the period of study?

    If yes, number of deviations

    Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

11. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC

    Yes ☐ No ☐ NA ☐

12. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

13. Briefly explain the reason for the extension sought (up to 500 words) (Please attach the relevant documents in support of the extension.)

Signature of PI:

Date:

Participant informed Consent Form

(Annexure 15)

Institute Ethics Committee
National Institute of Technology Meghalaya

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:_____

Participant Information Form

(Annexure 16)

Institute Ethics Committee
National Institute of Technology Meghalaya

EC Ref. No.* *(For office use):*

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:

REFERENCES

(1) Institutional Ethics Committee NEIGRIHMS, Shillong
(2) Institute Ethics Committee IIT Delhi
(3) Ethics Committee guidelines of All India Institute of Medical Sciences, Bhubaneswar
(4) ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017

	Name	Designation	Signature	Date
Prepared by	Dr. Gitish Kishor Dutta	Member Secretary		12/11/2024
Approved by	Prof. (Dr.) Manoj Kumar Choudhury	Chairperson		12/11/2024