STANDARD OPERATING PROCEDURE INSTITUTIONAL

ETHICS COMMITTEE, NEIGRIHMS

NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCES

Version 2.2

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Available at: the Institute website www.neigrihms.gov.in

NORTH EASTERN INDIRA GANDHI REGIONAL INSTITUTE OF HEALTH & MEDICAL SCIENCES

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INTRODUCTION

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

NEIGRIHMS complies with all the regulations as stated by CDSCO (DCGI) and also, New Drugs and Clinical Trials Rules, 2019 and other regulatory requirement of ICMR.

Today the ICH GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

In India, Ethics Committee for Research on Human Subjects presently functions according to the requirements laid down in New Drugs and Clinical Trials Rules, 2019 and is guided by the ICH GCP guidelines for Good Clinical Practice, ethical principles set forth in the Declaration of Helsinki and the Ethical Guidelines for Biomedical Research on Human Subjects laid down by Indian Council of Medical Research.

1. NAME OF THE ETHICS COMMITTEE

This Ethics Committee is known as **Institutional Ethics Committee, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences,** in short **IEC, NEIGRIHMS.**

2. AUTHORITY UNDER WHICH THE ETHICS COMMITTEE HAS BEEN CONSTITUTED:

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

3. MEMBERSHIP REQUIREMENTS OF ETHICS COMMITTEE:

a. The Chairperson and Members are nominated by the Institute Head based on certain criteria. The Chairman should necessarily be from outside Institute. Member Secretary should be from the Institute and willing to work as an Ethics Committee Member.
b. The period of Membership will be Three (3) years, or until they cease to be members either at their own request (or for any other reason mentioned under clause 6), whichever is earlier. However, this may be extended further if necessary. There should be always a mix of old and new members. For this purpose after completion of the tenure 25 - 50% members may be replaced
c. New members will be appointed to replace members who have resigned or whose tenures of membership have expired, according to the process described in Clause5, p-6.
d. Members should maintain confidentiality of all discussions during the meeting and signature confidentiality agreement at the start of their term.

4. TERMS OF REFERENCE OF THE COMMITTEE

Chairperson

a. The Chairperson of the committees shall be from outside the parent organization appointed by the Head of the parent organization.
b. The Chairperson will be responsible for conducting all Committee meetings and will lead all discussion and deliberations pertinent to the review of research proposals.
c. The Chairperson will preside over all the matters pertinent to the Committee's functions.
d. In Emergent situation, the Chairman will nominate a Committee Member as Chairperson OR in case of absence of the Chairperson, it is better that the member select an acting chairperson among themselves preferably from the outside of the Institute to avoid

conflict of interest.

e. The Acting Chairperson will have all the powers of the Chairperson for the respective meeting.

Member Secretary

1. The Member Secretary will be nominated by the Head of the Institute from the Members; he/she may be drawn from the parent organization.
2. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions:
   i. Inviting all the Committee members to come on board.
   ii. Receiving all the research proposals.
   iii. Forwarding all the documents to be reviewed to the Committee members
   iv. Preparation and dissemination of agenda for all Committee meetings 7(seven) days or less than 7 (seven) prior to the meeting date as per Clause 6 (Meetings: 5), p-19.
   v. Inviting special attendees from relevant area including therapeutics, of the scheduled meetings, if needed.
   vi. Preparation and circulation of minutes within seven (7) working days from the date of the meeting.
   vii. Notification of review outcome to Principal Investigator or Sponsor or CRO of research proposals within seven (7) working days from the date of finalization of the minutes of the meeting.
   viii. Generate and dispatch review letters of respective research proposals.
   ix. Retention and safe keeping of all records and documentation
   x. Performance of other duties assigned by the Chairperson.
   xi. Administrative matters pertinent to the Committee's functions.
   xii. Signing on behalf of the Chairperson, in consultation with the Chairperson.
   xiii. Doing all the communications on behalf of the Committee.

Alternate Member Secretary may be appointed from within the regular members in order to assist/fulfill the role of the Member Secretary in his/her absence.

In case of anticipated absence of the Member Secretary, the Acting Member Secretary will be nominated by the Chairperson and / or the Member Secretary and documentation for the same will be maintained. The Acting Member Secretary will perform the duties of the Member Secretary and have all the powers of the Member Secretary for that meeting.

5. CONDITIONS OF APPOINTMENT, TENURE AND THE QUORUM REQUIRED

Conditions of Appointment:

i. A member should be willing to reveal his/ her full name, profession and affiliation; all reimbursement for work and expenses, if any, within or related to the Committee, as these details will be made available to the appropriate authority upon request.

ii. A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

Appointment of New Members:

New members will be appointed under the following circumstances.

i. When a regular member completes his/her tenure.

ii. If a regular member resigns or drops out before the tenure is completed.

iii. If volume of proposals and frequency of review demands appointment of new members. When a new member shall be appointed, it is advisable to induct a member in the same category to fulfill the norms the same category.

Tenure of Membership:

i. The tenure of Committee Membership will be a continuous period of 3(three) years.

ii. Extension of membership will be decided by Head of Institute.

iii. There will be limit to the number of times that membership can be extended. To avoid Conflict of Interest (COI) and to bring new ideas and dimensions in the review, the extension should be limited to 2 times.

Quorum of Committee:

The regular member of the committee will ideally include at least 7 and maximum of 15 individuals as follows:

i.	Chairperson:	1
ii.	Member Secretary from the Institute:	1
iii.	Basic Medical Scientist (Preferably a Pharmacologist):	1-2
iv.	Clinicians from the Institute:	1-2
v.	Legal Expert:	1-2
vi.	Social Scientist/Social Worker/Ethicist:	1-2
vii.	Lay Person preferentially a nonprofessional lady from the community:	1-2

a. The Committee will have representation from both men and women.

b. All members will act in the manner independent of any influence of the existing relationship with any organization, institute or individual.

Quorum

A minimum of five members should be present in the meeting room. The quorum should include both medical, non medical or technical or/and non-technical members. Minimum one non-affiliated member should be part of the quorum and preferably at least one lay person should be present. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements. No decision is valid without fulfillment of the quorum.

Special Invitees

As appropriate, the Committee will decide the need for participation of qualified special invitees to have unbiased scientific and/or ethical opinion for the study protocol to be discussed. Special invitees shall participate in the discussion and deliberations, but will not vote on a research proposal. However, the opinion of the special invitee shall be recorded.

6. PROCEDURE OF RESIGNATION, REPLACEMENT AND REMOVAL OF MEMBERS

The membership will stand to be terminated under the following circumstances:

i. If a member resigns from the Committee

ii. If a member is incapable of performing his/her duty as a committee member.

iii. In case of demise of a member.

iv. Rotation system for membership will be considered to allow for continuity, development and maintenance of expertise with in the Committee and regular input of fresh ideas and approaches.

v. Any member may resign before completing their terms by writing their intention to the Chairperson/Head of the Institute, preferably a month prior.

vi. A member may be removed from the EC for unsuitable conduct or unethical behavior. Complaints against any member may be addressed to the Head of the Institution, who may decide to constitute a committee to look into the complaint. The views of the EC member would also be sought before any decision is taken.

7. ADDRESS OF THE OFFICE OF ETHICS COMMITTEE

Office of the IEC
First Floor (near Exam Cell)
Administrative Block, NEIGRIHMS, (North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences), Mawdiangdiang, Shillong, East Khasi Hills, Meghalaya - 793018

Email: subdean-ethics@neigrihms.gov.in
Email: membersecy-iec@neigrihms.gov.in
Email: iec.neigrihms@gmail.com

Website: www.neigrihms.gov.in
Telephone No: +91 364 2538013

8. STANDARD OPERATING PROCEDURE TO BE FOLLOWED BY THE COMMITTEE IN GENERAL

Name, Formation & Registration:

This Ethics Committee is known as **Institutional Ethics Committee, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, in short IEC, NEIGRIHMS.**

It has been registered with:

a. Central Drugs Standard Control Organization (CDSCO), Govt. of India vide registration No.ECR/978/Inst/MG/2017/RR-21 dt.07.12.2021 and with the

b. National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR), vide No.EC/NEW/INST/2022/ME/0138 dt.30.08.2022.

Objectives and Responsibilities:

The primary objective of this committee will be:

i. To protect the right, safety and well being of the research subject and assist in welfare and benefit of the society.
ii. To review the qualifications of all investigators participating in the proposed research study.
iii. To keep all information submitted to them confidential especially, the proprietary information.
iv. To review all research proposals submitted to the committee within the specified time limits
v. To maintain concise but clear documentation of its use on the research proposals.
vi. To review the progress of each research project at appropriate and specified intervals and also review the summary of final report of the studies approved by them.

Functions & Operations:

Submission of the Research Proposals:

1. All communications with the Committee will be in writing (Physical and/or electronic)
2. Before receiving the review materials, it is advisable to obtain COI declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson and Members. If it is required by Sponsor/CRO/ Investigator/Institution. A copy of this agreement will be filed with the official records of the Committee and another copy will be returned to the Sponsor / CRO / Investigator / Institution.

   The IEC has adopted the e-Ethics Committee software which is a web-based IEC manager based on the ICMR common forms. All proposals approved by the NSAC and those multicentric studies which have been approved by other IECs may be submitted on this software throughout the year as per the instructions provided. IEC meetings will be scheduled at regular intervals depending on the submissions received. The forms need to be filled up online and the declaration form generated needs to be signed and uploaded. All the documents uploaded should be in pdf format. One printout of the IEC form (Project Initial Submission) which is generated on the portal, needs to be printed out and submitted, along with the signed declaration, the protocol and ICD to the office of the IEC, NEIGRIHMS. The CVs need to be uploaded in the portal only. If the print out is not submitted, the proposal will not be processed. Also, if there are any deficiencies on the documents submitted online, the same will be returned to the investigator to rectify and upload the necessary documents. Once submitted, the proposals will be reviewed by the members of the IEC and queries, if any, will be communicated to the researchers through the portal only. The queries need to be responded to and necessary changes made on the portal.
3. All the relevant revised documents which are resubmitted for review should be uploaded on the portal using the edit options.
4. In case of any amendment to the research proposal or any modification which is not suggested by the Committee and is not administrative, submission should be as directed in sub-clause 3 above.
5. The documents required for submission are the following:
   a) The protocol, which should contain the version number and short title of the study (as footer in all the pages) should contain all the information pertaining to the conduct of the study. In studies approved by the NSAC, the “NSAC submission format-section 1” will be considered the

protocol and should be submitted with a version number (e.g. 1.0) in the footer. If any changes are advised by the NSAC or IEC, the version number in the corrected document should be changed to (1.1 or 1.2 accordingly). For multi-centric studies, the protocol prepared by the lead centre would suffice (if there is no NEIGRIHMS-specific modification). The NSAC approval letter (or IEC approval from other center) needs to be uploaded too.

b) The informed consent form/document (ICD) should have the short title of the study, the language and version number in the footer, which needs to be changed if any modifications are suggested by the IEC. The ICD should have a detailed Participant Information Sheet (PIS) as the first part, which should be in very simple language, free of medical jargon. It should be addressed to the participant. Translation(s) into regional language(s), as appropriate, will have to be submitted. Translation certificates or a declaration by the investigator(s) vouching the authenticity of the translations will have to be attached too.

c) Investigator's Brochure (IB).

d) Undertaking by Investigator.

e) Subject recruitment procedures (e.g. advertisements), if applicable.

f) Available safety information.

g) Information about payments and compensation available to the subjects.

h) Investigator's current Curriculum Vita indicating qualification and experience.

i) Approval from competent regulatory authorities, wherever applicable

j) Copy of the Insurance Certificate, if applicable

k) DCG (I) clearance (whenever applicable).

l) Investigator's agreement with the Sponsor / CRO, if applicable

m) Health Ministry Screening Committee (HMSC)/Bhabha Atomic Research Centre (BARC)/Genetic Engineering Advisory Committee (GEAC)/Director General of Foreign Trade (DGFT) clearance wherever applicable.

n) Food and drug Administration (FDA) marketing/manufacturing license for herbal drug wherever applicable.

Prescribed Application Form for Clearance of Research Project by IEC:

a) Name of the Investigator/co-investigator with designation :

b) Name of the Department where research will be conducted :

c) Protocol of the proposed research involving human subjects/participants* :

d) Ethical issues in the study and plans to address these issues :

e) Copies of Proforma/Case Report Forms/Questionnaires/Follow-up Cards, etc :

f) Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language/English/ Hindi :

g) For any drug/device trial, all relevant publications/pre-clinical data and clinical trial data from other institutions within the country/other countries, if available :

h) Curriculum Vitae of all the investigators with relevant publications during the last five years:

i) Regulatory clearances (other than IEC, NEIGRIHMS), if required :

j) Details of Funding agency/sponsors and fund allocation for the proposed work :

k) An agreement to report only Serious Adverse Events (SAE) to IEC :

l) Statement of conflicts of interest, if any :

m) A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research :

n) Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants :

o) Agreement to comply with the relevant national guidelines for research in human genetic, transplantation etc. as and when applicable.

p) Any other information relevant to the study.

Signature of Principal Investigator (PI) Place:
Date:

Signature of Co-investigator(s) Place:
Date:

*** The protocols should include among other things the following:**

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

Procedure for Document Receipt & Handling:

1. Receiving the Study Documents - The Member Secretary will receive the study documents and other related documents in hard copies at the Ethics Committee office, submitted by the Principal Investigator / Institution / Sponsor / CRO.
2. Checklist for Submitted Documents - The Member Secretary will check the following:
    a. A Submission Letter addressing the Ethics Committee.
    b. Total number of copies of all documents.

Circulating the Documents

1. After checking for the completeness of the documents, the IEC staff will forward the proposals to the Member Secretary on the portal. These will be sent to the members for review prior to the meeting. Members may peruse the proposals and add their comments/queries on the portal.
2. The researcher(s) may be requested to appear before the committee to clarify the details pertaining to their proposals. However, the final queries (if any) will be uploaded on the portal by the MS after approval of the minutes of the meeting.

Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The Committee members shall review the proposal with reference to the following:

a) Scientific design of the study

b) Justification/Rational of the study

c) Selection criteria for subjects

d) Justification for use of placebo, if any

e) Potential benefits to the study subjects, predictable risks to the study subjects

f) Criteria for discontinuation/withdrawal of the subjects

g) Monitoring of serious adverse events

h) Compensation to the subjects for participating in the study

i) Subject recruitment procedures (e.g., advertisements), if applicable

j) Patient retention activities

k) Compensation for study related injury or death

l) Post trial benefits

m) Protection of privacy and confidentiality and plans for publication of results (positive or negative)

n) Statistical analysis

o) Informed consent document in English and regional languages

p) Competence of the Investigators, supporting staff and infrastructure facilities

q) Approval of regulatory authorities wherever applicable.

Safety Information

Adverse Event/Serious Adverse Event reporting may be required for

1. The protection of the subject
2. Proper use of drug once it is marketed.

Adverse Event (AE): Any untoward medical occurrence in a Patient or Clinical Investigation Subject administered the pharmaceutical product and which does not necessarily have a casual relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (Including an abnormal laboratory finding), symptom or disease temporarily associated with the use of the Medicinal (Investigational) Product, whether or not related to the Medicinal (Investigational) Product. Expected adverse event may be known to occur and is listed in the Investigational Brochure, Informed Consent, or General Investigational Plan; whereas Unexpected adverse event may not be listed in Investigational Brochure, Informed Consent, or General Investigational Plan, also not listed in a drug package insert.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is any untoward medical occurrence that at any dose:

1. Results in death
2. Is life-threatening: If subject was at substantial risk of dying at the adverse event time, or continued use of the device or other medicinal product which might have resulted in the death of the subject.
3. Requires inpatient hospitalization or prolongation of existing hospitalization: If subject requires admission to the hospital or prolongation of hospitalization was a result of adverse event.
4. Results in persistent or significant disability/incapacity: If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., significant, persistent or permanent change, impairment or damage or disruption in the person's body function/structure/physical activities and/or quality of life.
5. Result in a Congenital Anomaly/Birth Defect: If exposure to a medicinal product during

pregnancy may have resulted in an adverse outcome in the child.

6. Important medical event like allergic bronchospasm, blood disorders, seizures/convulsions, the development of drug dependence or drug abuse.
7. Required medical or surgical intervention (treatment) to prevent permanent impairment of a body function or damage to a body structure as a result of medicinal product usage.

Timeline for reporting of SAE as per New Drugs and Clinical Trials Rules, 2019

Responsibility of Investigator:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
Sponsor	Notification	-	-	-
DCGI Office	Notification	Report of Death+ Other SAE	-	-
Ethics Committee	Notification	Report of Death + Other SAE	-	-
Head of Institution	-	Report of Death+ Other SAE	-	-
Chairman of Expert committee at CDSCO Office	-	Report of Death Only	-	-

Responsibility of Sponsor:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
DCGI Office	Notification	Report of Death + Other SAE	-	The sponsor shall pay in case of clinical trial
Ethics Committee	Notification	Report of Death + Other SAE	-	
Head of Institution	-	Report of Death + Other SAE	-	
Chairman of Expert Committee at CDSCO Office	-	Report of Death Only	-	

NOTE:

1. In case if the sponsor fails to provide medical management/financial compensation to the subject, the Licensing Authority (DCGI) may after giving an opportunity to show cause why such order should not be passed and/or may suspend or cancel the clinical trial and/or restrict sponsor to conduct any further clinical trials in the country.
2. For SAE other than Death, trial subject will get the compensation.
3. For Death, nominee of the subject will get the compensation.

Responsibility of Ethics Committee:

Shall forward its report after due analysis on SAE with its opinion on the financial compensation (if any) to be paid by the sponsor to:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
DCGI Office	Notification	Report of Death + Other SAE	-	-
Chairman of Expert committee-at CDSCO Office	-	Report of Death Only	-	-

Responsibility of Expert Committee (CDSCO Office) & Licensing Authority (DCGI Office):

- The Expert Committee shall examine the report of death and gives its recommendations (including quantum of compensation) to the Licensing Authority within 30 calendar days of receiving the report from the Ethics Committee.
- After considering the recommendations of the expert committee, the Licensing Authority shall decide the quantum of compensation and issue an order (shall be paid by Sponsor) within 3 months of receiving the report of SAE.

All SAE should be submitted as per the format of New Drugs and Clinical Trials Rules, 2019 and Ethics Committee should analyze and forward its opinion as per procedures specified in New Drugs and Clinical Trials Rules, 2019.

Criteria for the Approval of Research

In order to approve the research proposal, the Committee shall determine that all of the following requirements are satisfied:

1. Risks to subjects, if any, are reasonable in relation to anticipated benefits. In evaluating risks and benefits, the Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
2. Selection of subject is equitable. In making this assessment, the Committee should take into account the purposes of the research and the setting, in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children prisoners, pregnant women, mentally disabled persons, or economically or educationally or educationally disadvantaged persons.
3. Informed consent will be sought from each prospective subject or the Legally Authorized Representative of the subject.
4. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
5. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
6. In case, in which the documentation requirement is waived, the Committee may require the Investigator to provide subjects with a written statement regarding the research.
7. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
8. The Committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reason/s for the Committee's action and shall be reported promptly to the Investigator, appropriate institutional officials, the department or agency head.

Meetings

1. The Committee will hold regular meeting, depending on the number of research proposals for review. However the committee will meet at least once every 3-4 months.
2. The MS, in consultation with the chairperson will decide on the total number of proposals which may be discussed in one meeting. The timings for the meeting may be decided upon accordingly. The Member Secretary will check the availability of the members for the meeting and shall invite the members for the same accordingly.
3. Primary reviewer may be assigned by the chairperson/secretary to conduct a detailed review of a research protocol and provide a report at the meeting
4. All regular members will receive notification of meeting schedules at least five (5) days in advance. In case of molecule/combination of molecules which has already been discussed earlier by the Committee and/or the molecule/active ingredient that have been in case for considerable period of time, review meeting for such protocols/studies can be scheduled well within five (5) days or short notice as per availability of members. Towards the same, a list of molecules reviewed will be updated on regular basis for ready reference.
5. The proposal may be sent to a subject expert for his/her assessment and opinion of the research proposal. The subject expert may be invited for the meeting if deemed necessary by the Committee.
6. The Investigator and/or Co- Investigator may be invited to the meeting to provide clarifications on the study protocol if deemed necessary by the Committee.
7. Specific patient group representatives may also be invited for the meeting based on the requirement of the research area if deemed necessary e.g., Subjects with HIV/AIDS or genetic disorders etc.
8. Meeting will be held only if quorum is met. A quorum will be defined as a minimum of 5 (five) members including one basic scientist (preferably a pharmacologist), one clinician, one legal expert, one social worker/ representative of a non – governmental organization / theologian or a similar person, one lay from the community.

Minutes

The proceedings of the meeting will be recorded in English and in the form of minutes. The Member Secretary will be responsible for coordination, recording and circulation of the meeting minutes.

Decision Making

1. Decision for each proposal/study shall be individual voting.
2. All members present at the meeting will vote on the research proposal.
3. The decision will not be declared until the consensus is reached amongst all the members regarding the opinion to the proposal/study under consideration.
4. The queries, comments or suggestions from the member(s) not in favour of the approval, shall be forwarded to the Sponsor/CRO/Principal Investigator and reply received from their end will be discussed with members. After all the members(s), are satisfied with the reply, the chairperson shall take the final decision regarding further action on the protocol depending on the opinion/decision which is favoured by majority of the quorum members present at the meeting.
5. Absent members will not have a right to vote. However, if absent members have been a part of the entire discussion via any electronic media from (e.g. telecom, webcam etc.). They will be eligible to vote.
6. Member(s) of the Committee who is/are listed as investigator(s) on a research proposal will recuse themselves from all deliberations on the proposal and will not vote on the proposal.
7. An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the Committee.
8. The Committee shall reserve the right to withhold favorable opinion/approval on a research proposal when the Committee does not have reasonable assurance about the qualification of the Investigator(s), the site facilities, the Sponsor/CRO or the research protocol itself.
9. The Committee shall notify the Investigation/Sponsor/CRO in writing of its decision to approve or disapprove the proposed research activity. If the Committee decides to disapprove a research activity, it shall include in its written notification, a statement of the reasons for its decision and give the Investigator/Institution/Sponsor/CRO an opportunity to respond in person or in writing.

Review Outcome

The Committee will document its view as the following:

1. Approval–Unconditional or Conditional
2. Request for Modification or Information
3. Disapproval
4. Termination/Suspension of the research proposal/on-going study

Notification of Review Outcome

The outcome of the Committee review will be recorded and conveyed to the Investigator/CRO/Sponsor With in 14 (fourteen) working days from the date of review.

Approval Period

All projects will be given approval for a period of 1 (one) to 3(three) years from the date on which the project was approved and for the projects continuing further, renewal will be mandatory. Annual reports (or completion reports) will have to be submitted mandatorily for all studies.

Procedures for Appeal after Protocol Rejection

For research proposals rejected by the Committee, the applicant may appeal for a repeat review in writing, within Twelve (12) weeks of the receipt of the Committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the Committee.

Amendments to the Approved Research Proposal and Informed Consent Documents

1. All amendments to the approved research proposal shall be submitted to the Committee immediately for its review as directed in Clause 8 (Functions & Operations: sub-clause (4 &5), page-10.
2. No changes in the protocol and/or Informed Consent Documents shall be initiated without prior written approval from the Committee, except when necessary to eliminate immediate hazards to the subjects, or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of monitor(s), telephone number(s)].

Clause	Research Type	Example
1	Research involving information freely available in the public domain.	Published biographies, newspaper accounts of an individual's activities and published minutes of a meeting which would not be Considered 'personal data'
2	Research involving anonymized records and data sets that exist in the Public domain.	Data sets available through the offices of National and State agencies where Appropriate permission have already been Obtained and it is not possible to identify individuals from the information provided.
3	Studies of public behavior that are purely observational.	All non-invasive and non-interactive studies where the recorded observations do not identify individuals (names, photographs) which could place the matrix of harm, stigma or prosecution.
4	Research involving the use of non sensitive, completely anonymous studies.	All anonymous educational tests, survey and interview procedures when the participants are not defined as "vulnerable" and participation will not induce undue Psychological stress or anxiety.
5	Research involving the use of education tests, survey and interview procedures on human participants in the public arena.	All elected or appointed officials, candidates for public office, artists.
6	Taste and food quality evaluation & consumer acceptance studies. 'Exempt' doesn't apply to food evaluation studies where ethical issues related to local socio-religious and cultural practices of the studied Population may be a concern.	Studies where the food consumed is: a) wholesome without additives or b)contains a food ingredient, agricultural, chemical or environmental contaminant, for a purpose and at a level declared safe by the relevant National/State food safety agency.

In accordance with the above criteria, Departmental Research Committee of NEIGRIHMS will have to make the final judgment as to whether a particular activity should be submitted to IEC, NEIGRIHMS for a formal Ethics committee approval or just an 'Exempt'

***Note that exemptions above do not apply to research involving vulnerable participant.**

For example children and young people, those with a learning disability or cognitive impairment or individuals in a dependent or unequal relationship.

Expedited Review

The proposals presenting no more than minimal risk to research participants may be subjected to expedited review. The Member-Secretary and the Chairperson of the IEC or designated member of the Committee or Subcommittee of the IEC does expedited review only if the protocols involve:

1. Minor deviations from originally approved research during the period of approval (usually of one year duration).
2. Revised proposals previously approved through full review by the IEC or continuing review of approved proposals where there is no additional risk or activity is limited to data analysis.
3. Research activities that involve only procedures listed in one or more of the following categories:
    a. Clinical studies of drugs and medical devices only when:
        i. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
        ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
4. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.
5. When in emergency situations like serious outbreaks or disasters a full review of the research is not possible, prior written permission of IEC may be taken before use of the test intervention. Such research can only be approved for pilot study or preliminary work to study the safety and efficacy of the intervention and the same participants should not be included in the trial that may be initiated later based on the findings of the pilot study.
    a. Research on interventions in emergency situation when proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/devices/vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical

care could be allowed in patients when consent of person/patient/responsible relative or custodian/team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/legal guardian when available later;

i. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCFI;

ii. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

iii. If Data Safety Monitoring Board (DSMB) is constituted to review the data.

b. Research on disaster management: A disaster is the sudden occurrence of a calamitous event at any time resulting in substantial material damage, affecting persons, society, community or state(s). It may be periodic, caused by both nature and humans and creates an imbalance between the capacity and resources of the society and the needs of the survivors or the people whose lives are threatened, over a given period of time. It may also be unethical sometimes not to do research in such circumstances. Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities, and therefore, the following points need to be considered when reviewing such research:

i. Research planned to be conducted after a disaster should be essential culturally sensitive and specific in nature with possible application in future disaster situations.

ii. Disaster affected community participation before and during the research is essential and its representative or advocate must be identified.

iii. Extra care must be taken to protect the privacy and confidentiality of participants and communities.

iv. Protection must been sure so that only minimal additional risk is imposed.

v. The research undertaken should provide direct or indirect benefits to the participants, the disaster affected community or future disaster affected population and a priori agreement should be reached on this, whenever possible, between the community and the researcher.

vi. All international collaborative research in the disaster affected area should be done with a local partner on equal partnership basis.

vii. Transfer of biological material, if any, should be as per Government rules taking care of intellectual property rights issues.

Expedited Review Procedures

1. The Committee may use expedited review procedure in case of minor changes in the previously approved research. The expedited review may also be used when the amendments appear to involve no more than minimal risk to the study subjects.
2. Under the expedited review procedure, the review maybe carried out by the Chairperson, or by one or more experienced reviewers designated (as members of Expedited Review Committee) by the Chairperson from amongst the members of the Committee. There viewers may exercise all the authorities of the Committee except that the reviewers may not disapprove the research.
3. An on-going research activity may be disapproved only after review in accordance with non-expedited review procedure as mentioned. The members will be informed about the expedited review proposal in next full board meeting.
4. Only the Chairperson shall make the decision to allow an expedited review. Hence all studies ought to be submitted as for full board review. Expedited review may be considered on a written request to the MS citing the valid reasons.

Review of On-going Studies

The Committee will conduct continuing review of each on-going study at intervals appropriate to the degree of risk to the human subjects, but not less than once a year, and can also have authority to observe or have a third party observe the research activities.

1. The investigator should promptly report the following to the Committee:

    i. Deviations from or changes to the protocol to avoid immediate hazards to the trial subjects.

    ii. Deviations/changes that increase the risk to subjects and/or affect significantly the conduct of the trial.

    iii. All serious and/or Unexpected Adverse Events should be reported to the Committee by the Investigator within 24 hours of their occurrence as per applicable regulatory guidelines. The report of the serious adverse event of that or severe adverse event other than that after due analysis should be submitted within 10 (ten) calendar days of occurrence.

    iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.

2. In addition, the Investigator should submit the progress report of the study at intervals appropriate to the degree risk to the human subjects or as directed by the Committee.

3. In case of serious adverse event of death or other serious adverse events, the Committee will meet as and when required, in the view of recent amendment by CDSCO. The Committee may also invite an expert for his/her opinion on the same. The Committee will generate the report after due analysis and submit the same to the applicable authority within timelines specified in the applicable regulatory guidelines.

Annual Progress Report

1. For the study continuing for longer than the period of one year, the first report shall be submitted within thirty (30) days of completion of one year following the date of the first approval.
2. Subsequent report shall be submitted at one year intervals following the first report.
3. The Committee can recommend termination of ongoing clinical trials for the reasons like patient's safety, breach of any condition of approval, non-compliance on part of the Investigator, goal of the study achieved midway, complaint from the subject etc.

Annual Renewal Process

For studies, whose duration is more than one year, an extension of approval shall be given, after the status report and all other relevant reports mentioned are reviewed and approved by the Committee by the Annual Renewal Process. The approval for extension for study will be given for a period of one year.

Records Retention

The Committee will retain the following records;

1. Standard Operating Procedures (SOPs) in effect at the time of review and the previous SOPs.
2. Membership list at the time of review and the previous membership records.
3. Occupation/affiliations of the members at the time of review with CVs and training records of the members as well as CV of guest expert members.
4. Invitation Letter, Consent Letter and CDA signed by members and guest expert members and Resignation Letters of the members who have resigned.
5. Agenda of meetings, minutes of meetings and all correspondence with the Principal Investigator.
6. Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the

proposals, approved sample consent documents, progress reports submitted by the Investigators, reports of injuries to the subjects etc.

7. Applicable regulatory guidelines.
8. Registration details of the Ethics Committee.

Archival Policy

1. The Committee reference study documents and other related documents will be archived for 5 (five) years after the completion of the study. And after 5 (five) years, the respective Principal Investigator/Sponsor/CRO will be informed about the end of archival period and the documents will be returned or discarded as instructed by the respective authority.
2. The Archival Log will be updated accordingly.
3. The documents will be archived within a secure place in a locked cupboard with restricted access.
4. The documents of the completed study can be archived at a separate facility and the details for the same will be maintained in the archival log.

Reports to the Relevant Regulatory Authorities

The Committee will make a yearly activity report for submission to the Relevant Regulatory Authorities upon request, which would include the following elements;

1. A quantitative evaluation of the activities of the Committee and list of proposals reviewed.
2. Status of each study proposal.
3. Statements of significant new findings provided to subjects.

Handling of Subject Queries

1. The subjects can call on the Committee Office number which is given in the Informed Consent Document.
2. Subject's queries shall be documented by the Member Secretary and the same shall be conveyed to the Chairperson. The reply of the Chairperson will be conveyed back to the concerned subject.
3. In case the subjects want to talk directly to the Chairperson, the Chairperson's number shall be provided from the Committee Office.

9. **STANDARD OPERATING PROCEDURE FOLLOWED BY THE COMMITTEE FOR VULNERABLE POPULATION:**

1. The committee will give special consideration to the proposals involving vulnerable population for protecting the right and welfare of vulnerable subjects. Potentially vulnerable groups may include.
    i. Medical, pharmacy, dental and nursing student, subordinates hospital and laboratory personnel, employees of the pharmaceutical company.
    ii. Members of the armed forces and persons kept in detention
    iii. Unemployed or impoverished person
    iv. Patients with in curable diseases
    v. Patients in emergency situation
    vi. Ethnic or racial minority groups
    vii. Homeless persons, nomads, refugees
    viii. Pregnant women, foetus and neonates
    ix. Decisionally incapacitated
2. The committee will include representation in selected vulnerable population if additional expertise is needed in reviewing and approving the proposed research that involves vulnerable subjects. The committee may work with these participants, to be part of the review process. The documentation for the same will be maintained.
3. The committee will follow the applicable regulation and guidelines in reviewing the research that involves vulnerable population as research subjects.
4. The Committee will ensure that adequate justification for the involvement of vulnerable subject is provided in the protocol and other pertaining document wherever applicable.
5. The new study submission including vulnerable groups as potential research participants will be reviewed by the full board meeting and cannot be reviewing under expedited procedures.
6. Subsequent review of amendment and continuing review applications involving vulnerable group as potential research participants can be reviewed by expedited review procedures.

10. POLICY REGARDING TRAINING OF NEW AND EXISTING MEMBERS

1. The Chairperson will identify the training requirements of the Committee members.
2. The Chairperson and the Member Secretary will organize at least one workshop or training program for the Committee members every year.
3. The type of programs, areas for training and mentors for these workshops/training programs will be decided by the Chairperson in consultation with the Committee members.

11. POLICY TO MONITOR AND PREVENT THE CONFLICT OF INTEREST

1. The Committee Member with conflicting interest should not accept the protocol for review. The same should be communicated to the Member Secretary/Chairperson/Committee.
2. In case the member has conflict of interest for any protocol received for review, the member shall immediately inform Member Secretary/Chairperson/Committee well in advance of the scheduled meeting and withdraw from the meeting or withdraw from deliberation of that particular protocol. Another suitable member shall be invited to fulfill the quorum requirements.
3. If Committee members need information on the study from the member with a conflicting interest, then the member may remain present in the meeting room during presentation of the study. The member must then leave the meeting room during the deliberative discussion and voting of protocol.
4. The same will be recorded in the Declaration of Conflict of Interest Form and Minutes of Meeting.

DECLARATION OF CONFLICT OF INTEREST FORM

Investigator/Sponsor/CRO

Protocol No.:

Protocol Title:

Sl. No.	Member's Name	Designation	Conflict of Interest declared		Signature and Date
			Yes	No	

12. COMMITMENTS OF THE ETHICS COMMITTEE

1. The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for the safeguarding the rights, safety and well-being of the trial subjects.
2. In case of any SAE occurring to the clinical trial subjects during the clinical trial, the Committee shall analyse and forward its opinion as per procedures specified under New Drugs and Clinical Trials Rules, 2019
3. The Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization (CDSCO) to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query by such inspectors or officials, as the case maybe, in relation to the conduct of clinical trial.
4. The Committee shall agree to maintain adequate and accurate record after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (both in hard and soft copies).

13. FEES FOR IEC REVIEW

The competent authority has decided to levy a fee of Rs. 30,000/- plus GST 18% towards IEC review of all new proposals which are sponsored by the (Pharma and other) Industry. This would not apply to studies sponsored by Government and non-governmental agencies. The details for payment would be provided in the annexure.

14. REVIEW & REQUEST FOR REVISION OF THE EXISTING SOP

1. Any member of IEC or Investigator of NEIGRIHMS who notices any inconsistency or has any suggestion on how to improve a procedure should communicate through the Member Secretary/Chairman of the IEC.
2. If IEC agree with the request then appropriate team will be designated by the Director NEIGRIHMS and Chairman of IEC, NEIGRIHMS to proceed with the revision process. If Committee does not agree the Member Secretary will inform the person who made the request for the decision.
3. 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.
4. The Member Secretary will review the SOP at least every two years and incorporate the addendum and record the date of review in the SOP master file.

15. GRIEVANCE REDRESSAL

Any researcher or research participant who has any grievances against the IEC or members of the IEC may address their grievances in writing (or by email) to the Chairperson or Member Secretary. If not satisfied with the response, they may write to the Director, NEIGRIHMS, who is the appellate authority. All grievances should have the name and contact details of the aggrieved (complainant) and details of the nature of the grievance.

16. IMPLEMENTATION & DISTRIBUTION OF SOP

The approved SOP will be implemented from the effective date and will be available in the NEIGRIHMS website (www.neigrihms.gov.in). With the release of the new version of the SOP, the older version will no longer be effective.

17. REFERENCES

1. WHO Operational guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) Available at https://www.who.int/tdr/publications/documents/ethics.pdf (Accessed on 28th November 2021)
2. International Conference on Harmonization, guidance on good clinical practice (ICHGCP) (1996). Available at https://www.ich.org/LOB/media!MEDIA482.pdf (Accessed on 28th November 2021)
3. ICMR Ethical Guidelines for Biomedical Research on Human participants, ICMR (2018) Available

   at

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

   (Accessed on 28thNovember 2021)
4. NewDrugs_CTRules_2019.pdf – CDSCO. Available

   at

   https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf (Accessed on 28th November 2021)

Institutional Ethics Committee (IEC) North Eastern Indira Gandhi Regional Institute of Health and Medical Education Science (NEIGRIHMS), Shillong – 793018, Meghalaya	
SOP Title: Preparing Standard Operating Procedure (SOP): Writing, Reviewing, Distributing &Amending SOP for the Institutional Ethics Committee (IEC)	
SOP No: IEC/SOP/000/02.2	*Page 1 - 34*
Effective Date: 11th March 2025	

Prepared by

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Approved by

Dr. Sandra Albert
Chairperson, IEC, NEIGRIHMS, Shillong

Prof. (Dr.) Nalin Mehta
Director, NEIGRIHMS, Shillong

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Date: 11th March, 2025