STANDARD OPERATING PROCEDURES (SOP) FOR INSTITUTIONAL ETHICS COMMITTEE (IEC)

Silchar Medical College and Hospital

PO Ghungoor, Silchar – 788014, Assam

Version : 1

Approved by

1. **Prof. B K Bezbaruah** - Principal cum Chief Superintendent, Silchar Medical College and Hospital
2. **Prof Shekhar Chakraborty** Retd Vice Principal , Silchar Medical College and Hospital

Contents:

1. Introduction:

Silchar Medical College and Hospital (SMCH) established in 1968 is one in an apex healthcare institution in Southern Assam catering to large swathes of population of the three southern districts of Assam and adjoining areas of states of Mizoram, Manipur, Meghalaya and Tripura. The mission of SMCH is to be a Centre of excellence in medical education for both the MBBS , MD, Paramedical course and Nursing course and to provide a high-quality community and patient-focused health care that is readily accessible, cost effective and as per the needs of the communities and offer scientific research opportunities.

Bio medical research involves a number of ethical issues that need to be addressed. The Institutional Ethics Committee (IEC) plays an important role in guiding researchers in the ethical aspects associated with the biomedical research. Apart from ethical issues, IEC will also aims to review the research proposals for the scientific relevance, monitoring of the research project and risk involved in research. The Institutional Ethics Committee of Silchar Medical College & Hospital shall monitor all the research works including clinical trials which will be conducted in accordance with the guidelines of New Drugs and Clinical Trial Rules, 2019 along with Indian GCP guidelines, ICMR guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), Central Drugs Standard Control Organization (CDSCO) requirements, Drugs and Cosmetic Act (1940) and Rules (1945) and other rules and applicable regulations and guidelines.

2 Objectives:

The objective of this SOP is to maintain effective functioning of the IEC and to ensure quality ,technical excellence ,consistent ethical review of all submitted biomedical research proposals and ongoing approved research studies involving human participants in accordance with the ICMR National Ethical Guidelines and New Drugs and Clinical Trials Rules 2019. The SOP will be modified periodically in accordance with changes in the government guidelines

Responsibilities:

1. To review the qualification of all investigators participating in the proposed research study.
2. To keep all information derived as a part of the study - confidential especially the proprietary information.
3. To review all research proposals submitted to the Committee within specified time limits.
4. To maintain proper documentation of the research proposals.
5. 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.

3 Authority under which IEC is constituted

The Ethical Committee of Silchar Medical College and Hospital – from here upon on being referred as IEC – SMCH is an Institutional standing ethics committee which functions independently. The Principal , Silchar Medical College and Hospital has been empowered to appoint the Chairperson and all the committee members, based on their qualifications, competence and experience in reviewing and evaluating the scientific and ethical aspects of biomedical research proposals. The tenure/ period of all IEC members will be for 2 years extendable if required.

4 A) Composition:

The number of members in IEC – SMCH may range from 7 to 15. The IEC will be multidisciplinary in composition and independent. As per the ICMR National Ethical Guidelines2017, IEC will have the following categories of members

a. Chairman – Non affiliated
b. Vice Chairman – Non affilated
c. Member Secretary- Affiliated
d. Basic medical scientist-Non-affiliated/affiliated - 1-2 members
e. Clinicians –Affiliated 1-2 members
f. Legal expert -Non-affiliated 1-2 members
g. Social Scientist /representative of NGO/ ethicist/theologian /Philosopher// - Non- affiliated - 1-2 members
h. Lay person from the community -Non-affiliated/affiliated 1-2 members

Depending upon the number of research proposals, 2 EC may be functional simultaneously working under a common SOP.

The Institution will provide the Infrastructure, staff members, Space and adequate support for functioning of the EC. The Member Secretary will be given sufficient time to prepare for the EC meetings and documentation of the deliberations.

4 B Requirements for IEC Membership

Every EC member must:

i. Provide an updated CV with signature
ii. Consent letter
iii. Be willing to undergo training or update their skills/knowledge during their tenure
iv. Members are expected to declare conflicts of interest, if any, before commencement of the meeting.IEC members should not take part in discussion or decision making on research proposals in which they are PI or Co –investigators or if there are any other conflicts of interest. This should be mentioned in the minutes of the meeting.
v. Sign a confidentiality and conflict of interest agreement/s;
vi. Be willing to place her/his full name, profession and affiliation to the EC in the public domain
vii. Members are expected to show their full commitment, responsibility, respect for divergent opinions, maintain confidentiality review proposals from bias and without any external influences.

viii. All IEC members are to be familiarized with guidelines related to research and ethics such as ICMR National Ethical Guidelines2017, New Drugs and Clinical Trials Rules 2019, ICH-GCP guidelines. When there is any change in SOP the same will be communicated to the members and necessarytraining will be imparted.Record will be maintained regarding the training of members and change in the SOP/guidelines.

4 C Criteria for Selection of Ethics Committee Members

The Ethics Committee should fulfill the following criteria:

i. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with Silchar Medical College & Hospital.

ii. One member of the Ethics Committee who is not affiliated with the institute or organization shall be appointed by SMCH as the Chairman of IEC.

iii. One member who is affiliated with SMCH shall be appointed as the Member Secretary of the Ethics Committee.

iv. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of SMCH.

v. The members of the Ethics Committee shall follow the provisions of these rules, Good Clinical Practices Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.

vi. Every member of the Ethics Committee shall be required to undergo such training and development programmes as may be specified by the Central Licensing Authority from time to time.

vii. The members representing medical scientists and clinicians shall possess at least postgraduate qualification in their respective area of specialisation, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

viii. As far as possible, based on the requirement of research area such as Human Immunodeficiency Virus (HIV) or genetic disorder, specific patient group may also be represented in the Ethics Committee.

ix. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

x. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson.

xi. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

4 D APPOINTMENT OF MEMBERS:

The Members will be appointed under the following circumstances:

1. When a Regular Member completes his/her tenure.
2. If a regular member resigns or drops out before the tenure is completed.
3. If volume of proposals and frequency of review demands appointment of a new Member.
4. In case of demise of a Member.
5. Removal of a Member by the Head of the Institute.

It is advisable to induct a new Member in the same category of old one in place of whom the new member is appointed.

4 **E Tenure of membership:**

1. The tenure of Committee Membership will be a continuous period of 2(two) years.
2. Extension of Membership may be decided by the Head of the Institute.
3. There will be a limit to the number of times membership can be extended for a particular person. To avoid Conflict of Interest (COi) and bring in new ideas and dimensions, the extension may be for one time. However, the Head of the Institute may appoint a member for more than two terms, if he feels that such appointment is necessary for better functioning of the Committee.

4 F Procedure of resignation and removal of members:

1. Any Member may resign before completing his/her term by writing his/her intention to the Chairman. The Member has to serve notice at least one month before for consideration of his resignation. However, the Chairman shall review the same and decide whether to allow the member to leave the Committee with immediate effect or after serving the notice period of one month.
2. As per the report of the Member Secretary, the Head of the Institute may remove a member, if he/she fails to attend the Committee meeting continuously for 3 times or more.

5 Responsibilities of IEC – SMCH

The main responsibility of IEC – SMCH is to review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of research participants before approving the research proposals**.**

It should ascertain that all the ethical principles of research such as Autonomy, Beneficence, Non – maleficence, respect for free and informed consent, respect for human dignity, respect for vulnerable persons, respect for privacy and confidentiality and justice are taken care of in planning, conducting and reporting of the proposed research.IEC will review each study proposal for its both scientific and ethical review. The IEC will hold its meeting at predetermined intervals - approximately 3 (three) months ; and also monitor the ongoing research process. Expedited meeting of IEC can be held depending upon the urgency.

Members of IEC are expected to attended all IEC meetings and prior information should be provided if a member is unable to attend meeting.

5 A Responsibilities of each member is mentioned below

Member	**Responsibility**
Chairman – Non affilated Qualification A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and ensure active participation of all members during meeting • Ratify minutes of the previous meetings •Seek COI declaration from members and ensure quorum and fair decision making. • Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc. • Ensure quorum and fair decision making,
Vice Chairman- Non affilated Qualification A well-respected person from any background with prior experience of having served/ serving in an EC	Will conduct the meeting in absence of chairman Hold all the powers and responsibilities of chairman
Member Secretary - Affilated	Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule EC meetings, prepare the agenda and minutes • Organize EC documentation, communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required & adherence of EC functioning to the SOPs • Prepare for and respond to audits and inspections • Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. • Assess the need for expedited review/ exemption from review or full review. • Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. • Record discussions and decisions • Notification of review outcome to Principal Investigator or Sponsor of research proposals within 15 (fifteen) working days from the date of the meeting. • Administrative matters pertinent to the Committee's functions.
Basic scientist- Affiliated/ non-affiliated Qualifications - 1) Non-medical or medical person with qualifications in basic medical sciences 2) If reviewing clinical trials with drugs preferably a pharmacologist	• Scientific and ethical review - emphasis on intervention • benefit-risk analysis, research design, methodology and statistics, continuing review process, reporting of SAE, protocol deviation, progress • completion report, drug safety and

	pharmacodynamics in case of clinical trials
Clinician - Affiliated/ non-affiliated **Qualifications** 1. Should be individual/s with recognized medical qualification, expertise and training 2. For regulatory studies need PG qualifications	• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics • Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. • Thorough review of protocol, investigators brochure & all other protocol details
Legal expert - - Affiliated/ non-affiliated 1. Should have a basic degree in Law from a recognized university	Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc) compliance with guidelines etc. Interpret and inform EC members about new regulations if any
Social scientist/ philosopher/ ethicist/theologian- Affiliated/ non-affiliated Qualifications 1. Should be an individual with appropriate qualification, training and/or expertise 2. Be sensitive to local cultural and moral values. 3. Can be from an NGO involved in health-related activities	• Ethical review of the proposal, ICD along with the translations. • Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
Lay person- Non affiliated **Qualifications** • Literate person from the public or community • Has not pursued a medical science health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Involved in social and community welfare activities	• Ethical review of the proposal, ICD along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess on societal aspects if any.

The IEC has the right to revoke its approval accorded to scientific study/clinical study at any stage after citing the reasons for doing so and communicate the same to the Investigator as well as to the Licensing Authority/ other relevant stakeholders.

IEC will periodically review the progress of the approved studies till the completion of the study through periodic study progress report /internal audit reports. The study if scheduled for publication will have to take permission of IEC especially regarding patient privacy and data confidentiality.

The investigator is responsible for reporting all SAEs including hospitalization or prolongation of hospitalization, clinical trial related injury or death, regardless of causal relationship to the EC within 24 (twenty four) hours of knowledge. Reporting of SAE in details is to be done through email (including on non-working days) and in person. A report on how the SAE was related to the research must also be submitted within 14 days. SAEs must be reported for all trials and if applicable timelines as specified by regulators to be followed (within 24 hours to the sponsor, EC and regulator, if applicable, followed by a due analysis report in 14 days). The reporting is to be done in the prescribed form - *Annexure*

The IEC shall forward the report on any SAE(including, death), after due analysis, along with its opinion on the financial compensation, if any, to be paid by the sponsor or his representative, to the Chairman of the Expert Committee constituted by the Licensing Authority. The copy of the report has to be submitted the Licensing Authority within (21) twenty one calendar days of the occurrence of the SAE.

7 TRAINING OF IEC MEMBERS:

a) Purpose All IEC members are conversant with guidelines for Research involving Human Subjects.
b) Responsibility A team of trainers chosen for this purpose by the Member Secretary will ensure that new members get trained within a fortnight after being inducted.
c) Procedure All IEC members will be made conversant with ICMR Guidelines regarding Good Clinical Practice for Research involving Human Subjects as well as ICP-GCP Guidelines.

Training Schedule for new members of IEC, IEC-SMCH

SI. No.	Session Topic	Facilitator	Time Period
1	Role and responsibilities of IEC and its members	Member Secretary	**1** hour
2	Discussion on regulatory guidelines on IEC	IEC member nominated by Member Secretary	2 hours
3	Interactive session	With at least two members nominated by Member Secretary	2 hours

The Member Secretary of the IEC will collect the information on Drugs and Cosmetic rules, notifications and supplementary amendments from time to time and inform the Committee Members. Formal training in GCP along with certification will be organized at regular intervals.

8 QUORUM REQUIREMENT OF THE ETHICS COMMITTEE:

In general, the quorum of the Ethics Committee will be constituted by a minimum of five members of the committee.

However, no clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee unless at least five of its members as detailed below are present, namely:-

i. Medical scientist (preferably a pharmacologist);
ii. Clinician;
iii. Legal expert;
iv. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
v. Lay person

The Ethics Committee may constitute one or more sub-committees of its members to assist in the functions assigned to it. If the number of research proposals are more, 2 EC having the same mandate will function following a common SOP

The Ethics Committee may associate such experts, who are not its members, in its deliberations but such experts shall not have voting rights, if any.
Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licensing Authority within thirty working days.

9 INITIAL SUBMISSION PROCEDURES OF STUDY PROTOCOLS:

A Convention and Conduct of IEC meetings

1. The Chairman will conduct all meetings of the IEC – SMCH. In the absence of the Vice -Chairman who will conduct the meeting.
2. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned.
3. Member Secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members.
4. In the absence of Member Secretary alternate Member Secretary nominated by the Head of the Institute from among the members, will organize the IEC meeting.
5. All proposals will be received at least 3 weeks before the meeting and after initial scrutiny by Member Secretary the proposals will be circulated to the IEC members.
6. The recommendations by the IEC will be communicated to all the PIs and guides/HODs in case of student's proposals
7. If required additional review meetings can also be conducted with a short notice period.

B Application procedures

1. All proposals should be submitted to IEC on any working day *3 (three) weeks* in advance of scheduled meeting in the prescribed application form along with relevant documents – Annex
2. Eight (8) hard Copies soft copy of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators/ Collaborators / should be submitted to IEC
3. Principle Investigators shall forwarded their application to the Chairperson IEC, through Member Secretary and the receipt of the application will be acknowledged by the IEC office.
4. Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IEC meeting will be intimated to the PI to attend the meeting and to make a brief presentation of the proposal and to clarify the points raised by the members.IEC can suggest for online meetings and virtual presentations of the investigators in special situations .
5. If revision is to be made, the revised proposal in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
6. All research proposals/clinical trials funded/sponsored by Pharmaceutical companies, Agencies, Multinationals etc. will be charged an administrative fee/ processing fee of 5% of their sanctioned budget. Waiver of these fees is permissible for non-funded studies, departmental studies, and studies funded by organizations like ICMR, UGC, DST Government of India, State Science & Technology Department, UNICEF,WHO, USAID, Non Profitable Organizations etc.
7. Studies done in collaboration with SMCH will be charged @ Rs 1500 (Fifteen hundred) only per year.

C Procedure for document receipt and handling:

i) Receiving the Study Documents:

The Member Secretary will receive the study documents and other related documents in both hard and soft copies at the Ethics Committee Office, submitted by the Principal Investigator/ Institution/ Sponsor

ii) **Checklist for Submitted Documents: -** Annex

The Member Secretary will check the following:

1) Cover letter to the Member Secretary
2) Type of review requested
3) Application form for initial review
4) Permission of using copyrighted proforma/ questionnaire
5) A complete protocol
6) Approval of the project for Institute Scientific Committee
7) Informed Consent Form and its translated version into local language (in wordings the patient /guardian can understand).
8) Case record form/questionnaire

9) Recruitment procedures: advertisement, notices (if applicable)
10) Patient instruction card, diary, etc. (if applicable)
11) Investigator's brochure (as applicable for drug/biologicals/device trials)
12) Details of funding agency/sponsor and fund allocation (if applicable)
13) Brief curriculum vitae of all the study researchers
14) A statement on COI, if any
15) An Agreement to report any Serious Adverse Events (SAE) to IEC, SMCH.
16) Any other research ethics/other training evidence, if applicable as per EC SOP
17) Storage and maintenance of all data collected during the trial.
18) Undertaking with signatures of investigators
19) A statement specifying pecuniary risks involved and the measure(s) to be taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of New Drugs and Clinical Trials Rules, 2019 and national agencies), the researchers themselves and such other persons who may be directly or indirectly at risk in the conduct of the research.
20) Agreement to comply with national and international Good Clinical Practice (GCP) protocols for clinical
21) Safety measures to be taken during the proposed intervention by using any drug or vaccine to be tested, including information on results of relevant laboratory and animal research.
22) Regulatory permissions (as applicable)
23) Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
24) Relevant administrative approvals (such as HMSC approval for International trials)
25) Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
26) MoU in case of studies involving collaboration with other institutions (if applicable)
27) Insurance policy (if applicable)

iii) **Details of documents to be included in the protocol** (only applicable documents are to be submitted) - Annx

The protocol should include the following:

1. The first page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary of the protocol;
3. Background with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research objectives and end points/ outcome ;
6. Eligibility criteria and participant recruitment procedures;

7. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any;
8. Duration of the study;
9. Justification for use of placebo, benefit–risk assessment, plans to withdraw and rescue medication- if standard therapies are to be withheld,
10. Procedure for seeking and obtaining written informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Informed consent for storage of samples/assent/ re-consent
11. Plan for statistical analysis of the study;
12. Plan to maintain the privacy and confidentiality of the study participants;
13. For research involving more than minimal risk, an account of management of risk or injury;
14. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period and insurance policy
15. Provision of ancillary care for unrelated illness during the duration of research;
16. An account of storage and maintenance of all data collected during the trial; and
17. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity.
18. Ethical considerations and safeguards for protection of participants

10 **REVIEW PROCEDURE: BY IEC**

A Elements of Review

1. Scientific design and conduct of the study.
2. Approval of scientific review committee and regulatory agencies.
3. Assessment of predictable risks/harms and potential benefits.
4. Procedure for selection of subjects including inclusion/exclusion, withdrawal criteria and other issues like sample size and advertisement details.
5. Management of research related injuries, adverse events and compensation provisions.
6. Justification for placebo in control arm, if any.
7. Availability of products to the trial subjects after the study, if applicable.
8. Patient information sheet and informed consent form in English/Hindi and local language.

a. Protection of privacy and confidentiality of subjects.

9. Involvement of the community, wherever necessary.

10. Protocol and proforma of the study including the consent form.
11. Plans for data analysis and reporting.
12. Adherence to all regulatory requirements and applicable guidelines.
13. Competence of investigators, research and supporting staff.
14. Facilities and infrastructure
15. Different types of clinical research (Pharmaceutical, devices, Epidemiological, retrospective, Herbals, etc) are used depending on the research subject

B Review procedures

a. The meeting of the IEC will be held periodically, unless otherwise specified by the member secretary. Additional review meetings can also be held with short notice as and when required. Meetings will be planned in accordance with the need of the work load.
b. The proposals should be sent to the IEC at least 3 weeks in advance of scheduled meeting.
c. The Member-Secretary with the support of the secretarial staff shall screen the proposals for their completeness and depending on the risk involved categorize them into three types, namely, *exemption from review, expedited review and full committee review.*
d. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.
e. The PI / Research Scholar will then present the proposal in person in the meeting. When the PI is not available due to unavoidable reasons the Co-PI will be allowed to present the proposal. Researchers will be invited to offer clarifications on case to case basis, if needed
f. The review discussions/ decisions will be charted down and the final minutes will be approved by the Chairperson.
g. After the IEC meeting, the decision of the IEC members regarding the discussed proposals to obtained on the same day of the meeting.
h. The proceedings of the meeting will be video recorded with prior permission from all the members attending the meeting, if sought by the researcher.
i. The type of EC review based on risk involved in the research, is categorized as follows

Type of risk	Definition/description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. Research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater thanthat ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. 4. Routine research on children and adolescents; Research on persons incapable of giving consent 5. Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; 6. Use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; 7. Trying a new diagnostic technique in pregnant and breastfeeding women etc. 8. Research should have a social value. Use of personal identifiable data in research also imposes indirect risks. 9. Social risks, psychological harm and discomfort may also fall in this category
More than minimal risk or High risk	1. Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. 2. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures

C Types of reviews

a) Exemption from review

Following situations may come under this "less than minimal risk" category:

Research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

1. When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.
2. When interviews involve direct approach or access to private papers

b) 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 may do expedited review only if the protocols involve

1. Minor deviations from originally approved research protocol during the period of approval.
2. Revised proposal 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

I.Clinical studies of drugs and medical devices only when -

II. Research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.

III. Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes.

IV. 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 clinical trial that may be init iated later based on the findings of the pilot study.

4. Expedited review may also be taken up for nationally relevant proposals requiring urgent review.

c) 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 -

i. 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 be given to the relative/ legal guardian when available later;

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

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

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

d) Research on disaster management

It may also be unethical sometimes not to do research during disaster. 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 specificin nature with possible application in future disaster situations.

ii. Disaster-affected community participation before and during the research is essential and its representatives or advocates must be identified.

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

iv. Protection must be ensured 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.

e) Full Review

All research presenting with "more than minimal risk", proposals/ protocols which do not qualify for exempted or expedited review and projects shall be subjected to full review by all the members.

i. Research involving vulnerable populations, even if the risk is minimal;
ii. Research with minor increase over minimal risk
iii. Studies involving deception of participants;
iv. Research proposals that have received exemption from review, by subcommittee review should be ratified by the full committee, which has
v. The right to reverse/or modify any decision taken by the subcommittee or expedited committee;
vi. Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, case record forms etc.) involving an altered risk;
vii. Major deviations and violations in the protocol;
viii. Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
ix. Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
x. Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

f) Review of research proposals involving vulnerable population

Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. These include economically and socially disadvantaged; children (up to 18 years);women in special situations; tribals and marginalized communities; refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations; afflicted with mental illness and cognitively impaired individuals, differently abled –mentally and physically disabled; terminally ill or are in search of new interventions having exhausted all therapies; suffering from stigmatizing or rare diseases; or have diminished autonomy due to dependency or being under a hierarchical system and unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

IECs will carefully determine the benefits and risks of the study and examine the justification provided and risk minimization strategies

Additional safety measures will be strictly reviewed and approved by the IECs

IEC will ensure that the informed consent process is well documented and recording of assent in case of research studies involving children aged 7 to 18 years and reconsent, when applicable.

Informed consent from vulnerable populations may be obtained from LAR (Legally authorized representative)in presence of impartial witness after through explanation of risks and benefits,

g) Review of multicentric research

Multicentre research is conducted at more than one centre by different researchers usually following a common protocol.

- All sites are required to obtain approval from their respective ECs, which would consider the local needs and requirements of the populations being researched and safeguard the dignity, rights, safety and well-being of the participants.
- The ECs/Secretariats of all participating sites should establish communication with one another
- If any EC does not grant approval for a study at a site the reasons must be shared with other ECs and deliberated upon.
- The EC can suggest site-specific protocols and informed consent modifications as per local needs.
- Separate review may be requested for studies with a higher degree of risk, clinical trials or intervention studies where conduct may vary depending on the site or any other reason which requires closer review and attention
- Common review for all participating sites in multicentric research - In order to save time, prevent duplication of effort and streamline the review process, the ECs can decide to have one designated main EC, the decisions of which may be acceptable to other ECs.
- Common review process may be applied to research involving low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies determined to have low or minimal risk.
- The common review is applicable only for ECs in India. In case of international collaboration for research and approval by a foreign institution, the local participating sites would be required to obtain local ethical approval

11 Independent consultant/Invited subject experts

Subject experts will be called to provide special review for selected research proposals, if required. They can give their opinion/specialized views but they do not take part during decision making by IEC members.

12 Decision-making& Communication of decision

a. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived at, the decision will be made by voting procedure.
b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and the same should be conveyed to the Chairperson prior to the review of the application and recorded in the minutes.
c. Decision will be made only in meetings where quorum is complete.

d. Only the members can make the decisions. The expert consultants (subject experts) will only offer their opinions.

e. Decision may be to approve, reject, or revise the proposals. Specific suggestions for modifications and reasons for modifications and reasons for rejection will be given.
f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application revised will be specified.
g. Modified proposals will be reviewed by an expedited review through identified members.
h. Decision taken on the proposals will be communicated by the Member Secretary/secretariat in writing to the PI / Research Scholar within three weeks after the meeting at which the decision was taken in the specified format
i. IEC approval will be valid for one year or for the duration of the project whichever is less. Investigator has to get his or her project re- approved after one year, where required.
j. The communication of the decision will include:

a) Name and address of IEC-

b) The date, place and time of decision.

c) The name and designation of the applicant.

d) Title of the research proposal reviewed.

e) The clear identification of protocol no., version no., date, amendment no., date.

f) Along with protocol, other documents reviewed- Clear description of these documents along with Version No. and Date.

g) List of EC members who attended the meeting- clear description of their role, affiliation and gender.

h) A clear statement of decision reached.

i) Any advice by the IEC to the applicant including the schedule / plan of ongoing review by the IEC

j) In case of conditional decision, any requirement by IEC, including suggestions for revision, and the procedure for having the application re-reviewed.

k) In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.

l) Signature of the Chairperson and Member Secretary with date

13 Record keeping and archiving of documents

All Research proposals (8 hard copies along with soft copy) along with the information and

documents submitted will be dated and filed

The documents will be archived for a minimum period of 3 years and for sponsored clinical trials for 5 years after completion/termination of the study.

IEC members should not retain any documents with them after the meeting is over.

List of documents to be filed and archived

1. Constitution of IEC
2. SOP
3. CV & consent of IEC members
4. IEC Registration
5. Honorarium details, Income and expenses
6. Agenda & minutes of the meetings
7. One copy of proposal
8. Copy of recommendations/decision communicated to applicant
9. Review reports, documents received during the follow up period and final reports of the study

14 Terms of reference

Terms of reference will be maintained in the office of IEC. This includes

A. Membership Requirements

B. Terms of Appointment with reference to the duration of the term,

C. The policy for removal, replacement, resignation procedure**,**

D. Frequency of meetings, and

E. Payment of processing fee to the IEC for review, honorarium/ consultancy to the members/ invited experts etc.

The SOPs will be updated periodically based on the changing requirements. The term of appointment of members could be extended for another term and a defined percentage (35 to 50%) of members could be changed on regular basis. Preferably, IEC would appoint persons trained in bioethics or persons familiar with ethical guidelines and laws of the country.

15 Contact Details

Chairperson

Member Secretary

ANNEXURE 1 : Invitation letter to a member

Letter head

Letter ref no:

From

The Principal
Silchar Medical College and
Hospital
PO Ghungoor Silchar – 788014,
Assam

Sub: Invitation to be a member for Institutional Ethics Committee (IEC) of Silchar Medical College and Hospital

To

Dear Sir/Madam

Greetings from Silchar Medical College and Hospital

Based on your expertise in the field of medicine and research, you are cordially invited to be a member of our IEC for a period of two years or till further orders. I request you to kindly accept our invitation and confirm the same at the earliest.

This is issued with approval of competent authority.

With Regards

ANNEXURE - 2 Consent letter from a member

From,

To

The Principal
Silchar Medical College and Hospital
PO Ghungoor Silchar – 788014,
Assam

Sub: Consent to be a member of Institute Ethics Committee (IEC) -
Reg. Ref: Your Letter No: dated:

Dear Sir/Madam

With reference to your letter stated above, I hereby extend my willingness to become a member of IEC of SMCH, Silchar. I shall regularly attend IEC meetings to review and give my unbiased opinion regarding the ethical aspects of research proposals involving human participants.

I shall be willing for my name, profession and affiliation to be published.

I shall not participate in quorum decisions where there is a conflict of interest.

I shall maintain all the research project related information confidential and shall not share or reveal the same to anyone other than project related personnel.

I herewith enclose my CV

Thanking you,

Yours sincerely,

Signature with
date Name of the
Member
:

Address:

Telephone No: (Off) (Res)

email:

Annexure3: Appointment order

Date:

Ref No:

Dr/ Mr. / Mrs.:

I am pleased to appoint you as the ---------- of the Institutional Ethics Committee (IEC) (Human research) at Silchar Medical College and Hospital following the receipt of your acceptance letter. The appointment shall be effective from _____ for a period of ____ year / months or till further notice provided the following conditions are satisfied.

1. You should be willing to publicize your full name, profession & affiliation.
2. You are willing to record all reimbursement for work & expenses, if any, within or related to an EC & make it available to the public upon request
1. You consent to sign confidentiality agreement between you & the IEC regarding meeting deliberations, applications, information on research participants, & related matters.

Further, the renewal of your appointment will be by consensus & one-month notice on either side will be necessary prior to resignation/ termination of appointment. Terms & Conditions regarding the resignation procedure, disqualification procedures, replacement procedures etc. may be found in the Standard Operating Procedures (SOPs) of IEC- SMCH.

We sincerely hope your association with IEC- SMCH will be scientifically productive and beneficial to the Institute & the community at large.

Signature with date

ANNEXURE – 4 Annexure 4: Application for initial review

A. Basic information

(a) Title of the study:

Acronym/Short title,(Ifany):

(b) Name of Principal Investigator:

(c) Department:

(d) Date ofsubmission:

(e) Designation:

(f) Email id:

(g) Type of review requested:

Exemption fromreview Expedited review Full committee review

(h) Details ofInvestigators:

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

(i) Number of studies where applicant isa:

i) Principal Investigator at time of submission

ii) Co-Investigator at time of submission:

(k) Duration of the study:

FUNDING DETAILS ANDBUDGET

(a) Total estimated budget for site:

At site

Overall.

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

SECTION B - RESEARCH RELATED INFORMATION

1. OVERVIEW OF RESEARCH

(a)Lay summary(within300words):

(b) objective of the study:

(c) 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)*	☐		

(d) justification for conduct of this study:

1. METHODOLOGY

(a) Sample size/ number of participants

At site : total sample size

Control group / Study group

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

(b) Inclusion criteria:

(c) Exclusion criteria:

(d) Study design:

(e) Investigations specifically related to projects:

(f) Is there an external laboratory/outsourcing involved for investigations? Yes / No/ NA

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

Independent external review / Review by sponsor or Funder/Review within PI's institution / Review within multi-centre research group/ No review

Date of the Review:

Research Comments of scientific committee/IRC, if any (100 words)

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCHPARTICIPANTS

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/ Radioads/ ☐ Social Patients/ Family /Friends ☐ 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 under18yrs ☐ 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?

(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:

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) Does the study involve any financial outgo on the part of the participant?

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

Are adverse events expected in the study? Yes ☐ No ☐ NA ☐

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

b. If Yes, Specify

7. INFORMEDCONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons Yes/ No

(b) Version number and date of Informed Consent Form

(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 <7yrs 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/Counsellor ☐ Research Staff ☐ Other (*Specify*

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 in local language, please justify

e) Providedetailsofconsentrequirementsforpreviouslystoredsamplesifusedinthestudy[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 Secretary of EC ☐	

Others(Specify) ☐

8. PAYMENT/COMPENSATION

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

PI ☐ Institution ☐ Sponsor ☐ Otheragencies ☐ *(specify)*

(a) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ N/A ☐ If yes,then who will provide the treatment?

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

Sponsor ☐ Institutional/Corpusfund Projectgrant ☐ Insurance ☐

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

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

. Yes ☐ No ☐ N/A ☐

9. STORAGE AND CONFIDENTIALITY

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

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 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(Max50words) 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□

SECTION E: DECLARATION AND CHECKLIST

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 Guidelines for 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, New drugs and Clinical Trial Rules 2019 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 IEC 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 wherever applicable.

Name of PI:

Signature with date:

Name of Co-PI:

Signature with date:

Name of Guide:

Signature with date

Name of HOD:

Administrative requirements

S. No	Items	Yes	No	Enclosure No	IEC remarks
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	IEC clearance of other centres	☐	☐		

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	☐	☐		
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**
18	CTRI	☐	☐	☐	
19	DCGI	☐	☐	☐	
20	HMSC	☐	☐	☐	
21	NAC-SCRT	☐	☐	☐	
22	ICSCR	☐	☐	☐	
23	RCGM	☐	☐	☐	
24	BARC	☐	☐	☐	
25	others (specify)				

ANNEXURE 5 Application Form for Exemption from Review

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why exemption from ethics review is requested?

i. Research on data in the public domain/ systematic reviews or meta-analyses ☐

ii. Observation of public behaviour/ information recorded without linked identifier 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 ☐

vii. Any other (please specify in 100 words):

Signature of PI with date:

Comments of EC Secretariat:

Signature of Member Secretary with date:

ANNEXURE – 6 Continuing Review / Annual report format

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Date of IEC approval
2. Validity of approval
3. Date of start of study
4. Proposed date of study completion
5. Period of continuing report from to
6. Does the study involve recruitment of participants Yes ☐ No ☐

(a) If yes, Total number expected: Number Screened: Number Enrolled:.
Number Completed: Number on follow up

(b) Enrolment status – ongoing / completed/stopped

(c) Any other remark

(d) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ If yes ,total number withdrawn and reasons:

7. Is the study likely to extend beyond the stated period? Yes ☐ no If yes, please provide reasons for the extension.

8. Have there been any amendments in the research protocol /Informed Consent Document(ICD) during the past approval period?
If No, skip to item no.9 Yes ☐ No ☐

(i) If yes, date of approval for protocol and

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

If yes, when / how:

9. 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:

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

If yes, give details

11. Have any adverse events been noted since the last review? Yes ☐ No ☐
Describe in brief:

12. (a)Have any SAE's occurred since last review? Yes ☐ No ☐

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

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

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

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

If yes, number of deviations

b) Have you reported the deviations to EC? Yes ☐ No ☐

If no, state reasons

15. In case of multi centeric trials, have reports of off- site SAEs been submitted to the EC ?

Yes ☐ No ☐ NA ☐

16. Are there any publications or presentations during this period?

If yes give details Yes ☐ No ☐

Any other comments:

Signature of PI:

ANNEXURE – 7 Application/Notification form for Amendments

1. Title of the study

2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study

6. Details of Amendments

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

7. Impact on Benefit and risk analysis –
   Yes/No If yes describe in brief

8. Is any reconsent necessary? Yes/No
   If yes, have necessary changes been made in the informed consent? Yes/No

9. 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) ☐

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

    Signature of PI:

ANNEXURE – 8 Protocol Violation/Deviation Reporting Form (Reporting by case)

Title of the study

1. IEC ref no:
2. PI – Name, Designation and Affiliation

3. Date of EC approval
4. Date of Start of study
5. Participant ID

6. Total number of deviations /violations reported till date in the study:

7. Deviation/Violation identified by: Principal Investigator/study team/ Sponsor/Monitor/SAE Sub Committee/EC

8. Is the deviation related to(Tick the appropriate box):

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

9. Provide details of Deviation/Violation:

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

11. Impact on (if any): Study participant/Quality of data/

12. Are any changes to the study/protocol required?Yes/No

If yes, give details

13. Signature of PI with date

ANNEXURE 10 Serious Adverse Event Reporting Format (Biomedical Health Research)

Title of the study

1. IEC ref no:
2. PI – Name, Designation and Affiliation

3. Date of EC approval
4. Date of Start of study

5. Participant details:

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

6. Suspected SAE diagnosis
7. Date of onset of SAE:
8. Describe the event
9. Date of reporting SAE
10. Details of suspected intervention causing SAE
11. Report type: Initial/Follow-up/Final
12. If Follow-up report, state date initial report
13. Have any similar SAE occurred previously in this study? Yes/NO If yes, please provide details.
14. 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)

15 Tick which ever is applicable for the SAE:(Kindly note that this refers to the Intervention being evalua ted and NOT disease process)

A. Expected event/ Unexpected event

B. Hospitalization □ Increased Hospital Stay □ Death □ Congenital anomaly/birth defects □

Persistent or significant disability/incapacity □ Event requiring intervention (surgical or medical) to prevent SAE □ Event which poses threat to life □ Others □

15. In case of death, state probable cause of death.
16. No permanent / significant functional / cosmetic impairment □
17. Permanent/ significant functional/cosmetic impairment □ Not Applicable
19.

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).

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

21. Outcome of SAE

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

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

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

Signature of PI with date

ANNEXURE 11 Premature Termination/Suspension/ Discontinuation Report Format

1. Title of the study
2. IEC ref no:
3. PI – Name, Designation and Affiliation

4. Date of EC approval
5. Date of Start of study
6. Date of last progress report submitted to EC
7. Date of termination / suspension/ discontinuation:
8. Reason for Termination / Suspension/Discontinuation
9. Action taken post Termination /Suspension / Discontinuation (if any):
10. Plans for post study follow up/withdrawal(if any)
11. Details of study participants
    - Total number of participants to be recruited
    - Screened
    - Screen failures
    - Consent with drawn – reason
    - With drawn by PI- reason
    - Active on treatment / Completed treatment/ Participants on follow-up:
    - Participants lost to follow up
    - Number of drop outs
    - Reasons for each drop-out
    - Any other
12. Total number of SAEs reported till date in the study
13. Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes/No
14. Have there been participant complaints or feedback about the study? Yes/No If yes provide details
15. Have there been any suggestions from the SAE Sub Committee? Yes/No If yes have you implemented that suggestion? Yes/No

16. 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:

Signature of PI with date

Annexure 12: Application form for clinical trials

1. Title of the study

2. PI details

3. Type of Clinical trial – Regulatory trial / Academic trial

CTRI registration number:

NABH accreditation number:

EC registration number

4. If regulatory trial, provide status of CDSCO permission letter
   Approved and letter attached/ Applied, under process/ Not applied (State reason)

5. 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 study	☐
Non-drug intervention	☐	Repurposing an existing ntervention	☐
Indian system of (AYUSH)medicine	☐	Stem cells	☐
Phyto pharmaceutical drug		☐ Approved drug for any new indication or new route of administration	☐
Others (specify)			

6. 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.

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

8. 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:

9. 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	□		□

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

I. Drug/s, device/s and/or biologics; Yes □No □NA

if yes, provide regulatory approval details.

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. Yes □ No □ NA □

If yes, provide details.

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.

11. Describe in brief any preparatory work or site preparedness for the protocol? Yes □ No □ NA If yes, provide details

12. Is there an initial screening/use of existing database for participant selection? Yes□ No□ NA□If Yes, provide details

13. Is there any anticipated incidence, frequency and duration of adverse events related to the inter venation? Yes□No□NA□

If yes, provide details of arrangements made to address them.

14. Does the study use a placebo? Yes □No □NA □

If yes, justify the use of the placebo and risks entailed to participants.

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

If no, please justify.

16. Are there any plans to withdraw standard therapy during the study? Yes □ No □ NA □

If yes, please justify

17. Are there any rules to stop the protocol in case of any adverse events?.Yes ☐ No ☐

NA If yes, please specify

18. Does the study have a Data and Safety Monitoring Plan? Yes ☐ No ☐

NA If no, please justify.

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

English ☐ Local language ☐ Other(Specify) ☐

(certified that local version (s) is/are a true translation of the English version andcan be easily understood by the participants)

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 ☐

19. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration number? Yes ☐ No ☐

Please provide details.

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

Signature of PI with date

Annexure 13 Serious Adverse Event Reporting Format (Clinical trials)

1 Title of the study

i. PI details:
ii. Participant details
iii. Initials and Case No
iv. Subject ID
v. Age at the time of event
vi. Gender: Male/Female
vii. Weight (Kgs)
viii. Height (cms)

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

3. If Follow-up report, state date of Initial report

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

By PI – Related □ By Sponsor – Related□ By EC related

Unrelated □ Unrelated Unrelated

5 Describe the event and specify suspected SAE diagnosis

6. Date of onset of SAE: Date of reporting:

7. Onset lag time after administration of intervention:

8. Location of SAE (Clinic/Ward/Home/Other)

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

a. Suspect study drug (include generic name) device/intervention:
b. Indication(s) for which suspect study drug was prescribed or tested:

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

Therapy start date: Stop date:

11. Was study intervention discontinued due to event? Yes □ No □

12. Do the reaction decline after stopping or reducing the dosage of the study drug / procedure?

Yes □ No □ If yes, provide details about the reduced dose

13. Did the reaction reappear after reintroducing the study drug / procedure? Yes □ No □ NA

If yes, provide details about the dose

14. Concomitant drugs history and lab investigations:

a. Concomitant drug (s) and date of administration:

b. Relevant test/laboratory data with dates:

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

15. Have any similar SAE occurred previously in this study? Yes □ No

If yes, please provide details

16. Seriousness of the SAE: □ Death

□ Congenital anomaly

□ Life threatening

□ Required intervention to prevent

Hospitalization-initial or prolonged □ permanent impairment / damage □

Disability □ Others *(specify)* □

17. 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).

18. Outcome of □ Recovered □

SAE: Fatal

Continuing □ Unknown □

Recovering □ Other *(specify)* □

19. Was the research participant continued on the trial? Yes □ No □ NA □

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

21. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes □ No □

22. Provide details if communicated (including date)

23.Does this report require any alteration in trial protocol? Yes □ No □

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

Signature of PI with date

Annexure 14 Study completion/Final report format

Title of study:

PI (Name, Designation and Affiliation):

Date of EC Approval:

Date of Start of Study:

Date of study completion:

Provide details of

a) Total no. of study participants approved by the EC for recruitment:

b) b) Total no. of study participants recruited:

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

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

7. Describe in brief Plans for archival of records / Record Retention:

8. Is there a plan for post study follow-up –

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

10. Is there a plan for post study benefit sharing with the study participants?

11.Describe results (summary) with Conclusion:

12.Number of SAEs that occurred in the study

13. Have all SAEs been intimated to the EC:

14. Is medical management or compensation for SAE provided to the participants?

Annexure 15 INFORMED CONSENT DOCUMENT

A Participant information sheet

(i) Statement that the study involves research and explanation of the purpose of the research- In simple language

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the participant or others reasonably expected from research. If no benefit is expected participants should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the participant.

(vii) Statement describing the extent to which confidentiality of records identifying the participant will be maintained and who will have access to participant's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

(x)An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

(xi) The anticipated prorated payment, if any, to the participant for participating in the trial.

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

(xv) Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(d)Statement that the Participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of participants enrolled in the study.

(xvi) Any other pertinent information.

Additional elements, which may be required:

(a)Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b)Additional costs to the participant that may result from participation in the study.

(c)The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d)Statement that the Participant or participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the participant's willingness to continue participation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of participants enrolled in the study.

B Informed consent form

Study Title:

Study Number:

Participant's Initials: _____ Participant's Name: _____

Date of Birth/Age: _____

Address of the Participant ___

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate)

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

Place Initial box (Subject)

(i) I confirm that I have read and understood the information, Sheet dated _____ for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes

(v) I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study investigators name

Signature of the witness Date

Name of the witness Mobile No

Annexure 16 Undertaking By The Investigator

1. Full name, address and title of the Principal Investigator (or Investigators when there is no Principal Investigator).
2. Name and address of the medical college, hospital or other facility where the research will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained. I inform that no work has been started for this research yet.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subject, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s)in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with date.