UNITED INSTITUTE OF MEDICAL SCIENCES, PRAYAGRAJ, U.P.

STANDARD OPERATING PROCEDURES

FOR

INSTITUTIONAL ETHICS COMMITTEE

Version-1

2023 - 2025

Standard Operating Procedures (SOP)

For

Institutional Ethics Committee (IEC)

For United Institute of Medical Sciences, Prayagraj – 211012

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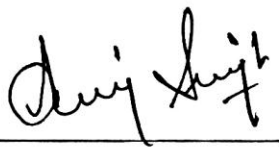
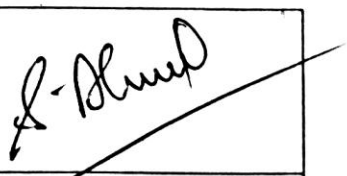
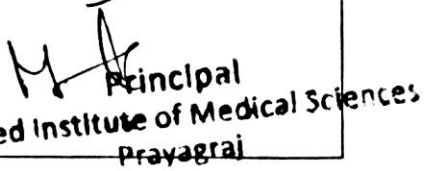
SOP Prepared by:

Dr. Anuj Singh Member Secretary IEC, United Institute of Medical Sciences, Prayagraj	

Reviewed by:

Dr. Ravi Kant Tiwari Professor & Head, Department of Pharmacology United Institute of Medical Sciences, Prayagraj	

Approved by:

Dr. Shabi Ahmed Chairperson IEC, United Institute of Medical Sciences, Prayagraj	
Dr. Mangal Singh Pricipal United Institute of Medical Sciences, Prayagraj	

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ABBREVIATIONS AND ACRONYMS

AE: Adverse event

COI: Conflict of interest

CRO: Contract research organization

DCGI: Drug Controller General of India

DGHS: Directorate General of Health

DSMB: Data and Safety Monitoring Board

DTA: Data transfer agreement

EC: Ethics committee

GCP: Good clinical practice

GOI: Government of India

ICD: Informed consent document

ICF: Informed consent form

ICMR: Indian Council of Medical Research

MoHFW: Ministry of Health and Family Welfare

MOU: Memorandum of understanding

MTA: Material transfer agreement

NDCT Rules 2019New: Drugs and Clinical Trials Rules, 2019

PIS: Participant information sheet

SAE: Serious adverse events

SOP: Standard operating procedure

TOR: Terms of reference

1. Introduction:

Name of the Ethics Committee:

This Ethics Committee is known as **Institutional Ethics Committee, United Institute of Medical Sciences,** in short **IEC, UIMS.**

Authority under which the ethics committee has been constituted:

The Principal, United Institute of Medical Sciences shall constitute the IEC in accordance with the SOP.

Purpose and scope of the proposed Ethics Committee.

The Institutional Ethics Committee (IEC) of the United Institute of Medical Sciences is established as an independent representative and competent body to provide independent guidance, advice and decision (in the form of "approval/recommendation /disapproval") and to ensure quality as well as technical excellence with consistent ethical review of all the submitted biomedical research proposals involving human participants in accordance with the ICMR ethical guidelines for biomedical research on human participants.

The primary purpose of this committee is to protect the rights, safety and well being of human subjects who participate in a research project.

Apart from ethical issues, IEC will also review the research proposals for the scientific relevance and risk involved in research. IEC functions as per the ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017 (ICMR National Ethical Guidelines).

Types of projects that will be reviewed under the purview of Biomedical and Health Research, if academic or investigator initiated studies.

The types of projects that will be reviewed under the purview of Biomedical and health research means studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioural); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined in New Drugs & Clinical Trials Rules- 2019

2. Membership requirements of Ethics Committee:

The composition of the IEC shall be multidisciplinary and multi-sectorial. IEC shall consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of the proposed research.

- 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.
- The number of members in the committee shall be kept in between 10-12 members for thorough review. A sufficient number of external members must be ensured to protect the independence of the committee.
- The committee will comprise of a Chairperson, a Member Secretary, and 8-10 other active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests.
- IEC shall ensure appropriate numbers of members from other institutions. They could be drawn from any public or private institute within the Uttar Pradesh. There shall be adequate representation of age, gender, community etc. in the Committee to safeguard the interests and welfare of all sections of the society. It is desirable to have representation of both the genders in the Committee.
- The members are selected in such a way as to have an equitable representation of all specialties in the institution. The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary should conduct the business of the Committee. Other members should be a mix of medical/non-medical, scientific and non-scientific persons including lay public to reflect the different viewpoints.

2.1. The composition Ethics Committee is as follows:

1. Chairperson - Non Affiliated
2. Member Secretary - Affiliated
3. Basic medical scientists - Affiliated / Non Affiliated
4. Clinicians - Affiliated / Non Affiliated
5. Legal expert - Non Affiliated
6. Social scientist/representative of non-governmental voluntary agency - Non Affiliated
7. Lay person from the community - Non Affiliated

3. Roles & responsibilities of each member are mentioned below:

Member	Responsibility
Chairperson	• 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.
Member Secretary	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 and 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. • Ensure quorum during the meeting and record discussions and decisions
Basic Medical scientist	Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report, drug safety and pharmaco-dynamics in case of clinical trials
Clinician	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	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.
Social scientist/ philosopher/ ethicist/theologian	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	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.

4. Conditions of appointment, term of reference, policy for payment and quorum requirements

4.1 Conditions of Appointment:

1. Name, age, gender, profession, and affiliation of IEC members will be used in public domain.

2. EC member to submit current CV and training certificates in human research protection and/or GCP or must undergo training and submit training certificates within 6 months of appointment

3. EC member must sign a confidentiality and conflict of interest agreements

4. EC member must be aware of relevant guidelines, regulations and willing to undergo training or update their skills/knowledge during their membership tenure.

5. EC member must be committed and understanding to the need for research and for imparting protection to research participants.

4.2 Terms of reference of the committee:

1. The members of the IEC will be appointed for duration of 2 years.

2. The appointment procedure for membership will be followed, so that it allows for continuity, the development and maintenance of expertise within the IEC, and the regular input of fresh ideas and approaches.

3. The members can be continued and there will be no limit on the number of times the membership is extended. Extension of membership will be based on the recommendation of the Chairperson & Member Secretary of IEC.

A Member Secretary, Chairperson or member may be newly appointed before the completion of the tenure of the existing appointed committee. This appointment will be effective for the remaining tenure of the existing committee

4.3 The policy regarding terms of payments

Non- affiliated members of Ethical Committee of the United Institute of Medical Sciences will be paid Rs.5000/- as remuneration for attending each IEC meeting. However, membership of ethical committee is additional responsibility for affiliated members without separate remuneration.

4.4 Quorum Requirements:

1. A minimum of five members present in the meeting room.

2. The quorum should include both medical, non medical or technical or/and non-technical members. (Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.)

3. Minimum one non-affiliated member should be part of the quorum.

4. Preferably the lay person should be part of the quorum.

5. No decision is valid without fulfillment of the quorum.

5. Procedure for resignation, replacement or removal of members

5.1 Resignation / Replacement procedure:

- IEC members who decide to resign must provide the Member Secretary or Chairperson the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting.
- A member can tender resignation from the committee with proper reasons to do so, which should be acceptable to the Member Secretary and members of the IEC.
- In case of resignation, Principal, United Institute of Medical Sciences would appoint a new member, falling in the same category of membership.
- The recommendations may be sought from the resigning member.
- Appointment may be made in the consultation with Member Secretary and /or Chairperson.

5.2 Termination / Disqualification procedure:

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

- Inability to participate in the meetings on any grounds.
- If a regular member fails to attend more than 3 meetings of IEC. The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Member Secretary by the Chairperson IEC for necessary action.
- Relocation to another city or any such matter. In all such situations/circumstances, Member Secretary will serve a letter of termination to the member.

6. Standard operating procedure to be followed by the committee in general:

6.1 Objectives and Responsibilities of the committee-

The primary objective of this committee will be:

1. To protect the right, safety and well being of the research participants and to assist in welfare and benefit of the society.
2. To review the qualifications of all investigators participating in the proposed research study.
3. To keep all information submitted to them confidential especially, the proprietary information.
4. To review all research proposals submitted to the committee within the specified timelimits.
5. To maintain concise but clear documentation of its use on the research proposals.
6. 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.

6.2 Functions & Operations-

Submission of the Research Proposals

1.All communications with the Committee will be in writing (Physical or electronic)

2.Before receiving the review materials, it is advisable to obtain COI declaration and CA (Confidentiality Agreement) from the Chairperson, Member Secretary & 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.

3.The Committee will require the submission in Printed (member copies + 1 PI Reference copy (if required) + Guest Member copy (if any) & electronic copy (whenever possible) of study dossier as listed for every research proposal.

All the relevant revised documents which are resubmitted for review should be submitted in two copies (Committee reference copy + one copy) if the resubmission involves only those changes which are suggested by the Committee with no other modification.

6.3 Prescribed Application Form for Clearance of Research Project by IEC:

a) Cover letter to the Member Secretary

b) Type of review requested

c) Application form for initial review

d) Permission of using copyrighted proforma / questionnaire

e) A complete protocol

f) Approval of the project for Institutional Research Committee

g) The correct version of the informed consent document (ICD) in English and the local language(s).

h) Case record form/questionnaire

i) Recruitment procedures: advertisement, notices (if applicable)

j) Patient instruction card, diary, etc. (if applicable)

k) Investigator's brochure (as applicable for drug/ biologicals/device trials)

l) Details of funding agency/sponsor and fund allocation (if applicable)

m) Brief curriculum vitae of all the study researchers

n) A statement on COI, if any

o) GCP training certificate (preferably within 5 years) of investigator .

p) Any other research ethics/other training evidence, if applicable as per EC SOP

q) List of ongoing research studies undertaken by the principal investigator (if applicable)

r) Undertaking with signatures of investigators

s) MoU in case of studies involving collaboration with other institutions (if applicable)

w) Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)

x) Insurance policy (if applicable)

6.4 The protocols should include among other things the following:

a) Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.

b) Subject recruitment procedures.

c) Inclusion and exclusion criteria for entry of subjects in the study.

d) Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedure, if any.

e) A description of plans to withdraw or withhold standard therapies in the course of research.

f) The plans for statistical analysis of the study.

g) Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant

laboratory and animal research.

h) Storage and maintenance of all data collected during the trial.

i) Agreement to comply with national and international GCP protocols for clinical trials.

6.5 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 including –

   a. Cover letter (To Member Secretary IEC)
   b. Project submission form
   c. Protocol (Complete research project)
   d. Case record form & Informed consent form (Hindi and or English)
   e. GCP certificate of Principal Investigator and Co-Investigators

3. Timeline for project submission; 15 days before the next meeting of the Institutional Research Committee and 30 days before the next meeting of the Institutional Ethics Committee.

6.6 Circulating the Documents

1. Study documents will be circulated to the members along with a Document Circulation Log to maintain the record of the same and the template of Document Circulation Log is given below.
2. The Document Circulation Log will be filed by the person receiving the documents.
3. After the documents have been circulated, Document Circulation Log will be checked for completeness and will be archived in master log file.

Annexure-1

IEC, UIMS

DOCUMENT CIRCULATION LOG

Sponsor / CRO;

Protocol No.:

Member's Name	Receiver's Name	Date	Signature

6.7 Return of the Documents:

I. On the meeting day, the members will bring their hard copies of the study documents to be reviewed.

II. After taking the decision for the proposed study, the members return their copies at the office.

III. All the returned copies will be discarded if not asked to be returned by the Investigator / Institution / Sponsor / CRO, except for two copies, one Committee reference copy and one copy to be kept with the Chairperson.

IV. Out of the two copies, one Committee reference copy will be archived at the Committee office and the Archival Log will be updated accordingly and the second copy will be kept with the Chairperson.

V. Archival will be done as per the archival policy of the ethics committee.

VI. In case a member is not able to attend the meeting, it will be the member's responsibility to return the documents to the Committee.

6.8 Review procedures-

Meetings:

1. 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 IEC.

2. The proposals should be sent to the IEC at least 4 weeks in advance of scheduled meeting.

3.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.

4. Decisions will be taken by consensus after discussion, and whenever needed voting will be done.

5. 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

6. The review discussions/ decisions will be charted down and the final minutes will be approved by the Chairperson.

7. After the IEC meeting, the decision of the IEC members regarding the discussed proposals will be obtained on the same day of the meeting.

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

9. The type of EC review based on risk involved in the research, is categorized as follows

6.9 Definition and categories of risk-

Type of risk	**Definition/description**
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, 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 than that 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. Examples include 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. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; 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; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. 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, etc.

6.10 Types of reviews-

Expedited review:

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 may be carried out by the Chairperson, or by one or more experienced reviewers designated by the Chairperson from amongst the members of the Committee. The reviewers 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.

Full review:

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

While reviewing the proposals, the following situations may be carefully assessed against the existing facilities at the research site for risk/benefit analysis:

a. Collection of blood samples by finger prick, heel prick, ear prick, or venipuncture:

i. from healthy adults and non-pregnant women who weigh normal for their age and not more than 500 ml blood is drawn in an 8 week period and frequency of collection is not more than 2 times per week;

ii. from other adults and children, where the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected has been considered and not more than 50 ml or 3 ml per kg, whichever is lesser is drawn in an 8 week period and not more than 2 times per week;

iii. from neonates depending on the haemodynamics, body weight of the baby and other purposes not more than 10% of blood is drawn within 48 – 72 hours. If more than this amount is to be drawn it becomes a risky condition requiring infusion/blood transfusion;

iv. Prospective collection of biological specimens for research purposes by noninvasive means.

For instance:

1. skin appendages like hair and nail clippings in a non-disfiguring manner;
2. dental procedures - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction of permanent teeth; supra and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth;
3. excreta and external secretions (including sweat);
4. uncannulated saliva collected either in an un stimulated fashion or stimulated by chewing gum or by applying a dilute citric solution to the tongue;

5. placenta removed at delivery;
6. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
7. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
8. sputum collected after saline mist nebulization and bronchial lavages.

b. Collection of data through noninvasive procedures routinely employed in clinical practice. Where medical devices are employed, they must be cleared/ approved for marketing, for instance-

i. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
ii. weighing or testing sensory acuity;
iii. magnetic resonance imaging;
iv. electrocardiography, echocardiography; electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow,
v. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

c. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

d. Collection of data from voice, video, digital, or image recordings made for research purposes.

e. Research on individual or group characteristics or behavior not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

6.11 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 to be 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.

6.12 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 favor 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 opt out from all deliberations on the proposal and will not vote on the proposal.
7. 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.
8. 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.

6.13 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 / ongoing study

6.14 Notification of Review Outcome:

The outcome of the Committee review will be recorded and conveyed to the Investigator / CRO/Sponsor within 7 (seven) working days from the date review.

7.15 Approval Period:

All projects will be given approval for a period of 1 (one) year from the date on which the project was approved and for the projects continuing for longer than one year annual renewal will be mandatory.

6.16 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.

6.17 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 per the **annexure-8**
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)].

6.18 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. (**Annexure-7**)

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.

6.19 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. (**Annexure-7**)

6.20 Records Retention:

The Committee will retain the following records;

1. Standard Operating Procedures (SOPs) in effect at the time of review and the previousSOPs.
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.

6.21 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.

6.22 Reports to the Relevant Regulatory Authorities.

The Committee will make an 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.

6.23 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.

7. Standard operating procedures to be followed by the committee for vulnerable population

7.1 Individuals may be considered as vulnerable if they are:

• socially, economically or politically disadvantaged and they are susceptible to being exploited;
• incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
• able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
• 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.

Following are some examples of vulnerable populations or groups:

• economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
• 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;
• children (up to 18 years);
• women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
• 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 (students, employees, subordinates, defence services personnel,

7.2 The Ethical Committee during the review process of projects involving vulnerable population, will determine whether the prospective participants for a particular research are vulnerable.

• The committee shall examine whether inclusion/exclusion of the vulnerable population is justified.

• The committee will ensure that COI do not increase harm or lessen benefits to the participants.

• The committee will carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible.

• The committee will suggest additional safeguards, such as more frequent review and monitoring, including site visits.

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

• Only the full committee will do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations.

7.3 Obligations/duties of stakeholders

Stakeholders	**Obligations / duties**
Researchers	• To recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • To justify inclusion/exclusion of vulnerable populations in the study. • To must address the COI issues. • To have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • To ensure that prospective participants are competent to give informed consent. • To take consent of the LAR when a prospective participant lacks the capacity to consent. • To respect dissent from the participant. • To seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • To conduct the research within the purview of existing relevant guidelines/regulations.
Ethics Committees	• During review the ethical committee, determine whether the prospective participants for a particular research are vulnerable. • To examine whether inclusion/exclusion of the vulnerable population is justified. • To ensure that COI do not increases harm or lessen benefits to the

	participants. • To carefully determine the benefits and risks to the participants and advice risk minimization strategies wherever possible. • To suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • EC has special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. The committee exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. EC will ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • EC has SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

8. 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 7 (seven) calendar days of occurrence.

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

v. 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.

vi. In case of serious adverse event of death or other serious adverse events, the Committee will meet as and when required. 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.

9. Review of serious adverse events (SAE) and unexpected adverse events (UAE) reports:

9.1 Adverse Event: "adverse event" means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given.

9.2 Serious Adverse Event: "serious adverse event" means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalisation of the trial subject where the trial subject is

an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event.

IEC reviews the SAEs the following the standard protocol – As per format mentioned in the New Drugs and Clinical Trials Rules, 2019 (Third Schedule Table 5)

9.3 Responsibility for review of SAE & UAE:

1. The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to research participants. In addition, the committee is authorized to offer medication under appropriate circumstances.
2. IEC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.
3. The Member Secretary is responsible for receiving the complete SAE / unexpected events reports and directing them to the members/designated expert reviewers for detailed review. The expert reviewers will prepare their report using Annexure-6 and based on the report from expert committee (reviewers) IEC will send the same with its opinion on the financial compensation (if any, determined in accordance with the formula specified) to the DCGI expert committee for review of SAEs and ratification in the IEC meeting.
4. Notifying the IEC does not relieve the PI from his/her responsibility to notify the sponsor, head of institute and regulatory authorities.

9.4 Detailed instructions about on site SAEs: SAE related activities before IEC meeting:

1. The Member Secretary/ Secretariat will verify that the SAE reports in the prescribed format are complete, signed and dated by the PI. In case he/she notes that the report is incomplete, it will be forwarded to PI, to revert with adequate data.
2. The IEC office should receive the initial reports of SAEs occurred for IEC approved studies within 24 hrs. Of the occurrence of the SAE. If the investigator fails to report any serious adverse event within the stipulated period, he/she will have to furnish the reasons for delay to the satisfaction of the regulatory authority along with the report of the serious adverse event. Follow up reports shall be received within 14 calendar days.
3. If the PI has not adhered to the above stipulated time period, the IEC office will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

9.5 Actions to be taken by Member Secretary:

1. The Member Secretary after receipt of the SAE Report will forward it to the designated reviewer within 1 working day for review.
2. Designated reviewer will review the SAE and communicate the opinion by e-mail or telephone/written report to inform the Chairperson / Member Secretary, IEC.
3. The Member Secretary will ratify the designated reviewer's report along with relevant documents from PI at the next IEC meeting.
4. The final review opinion of IEC will be communicated to DCGI within 30 days from the SAE report.
5. Compensation if applicable will be calculated as per formula specified in the New Drugs and Clinical Trial Rules, 2019 and ICMR guidelines.
6. Appropriate compensation will be given to the subject according to New Drugs and Clinical Trials Rules, 2019.

10. Review of multi-centric 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. Conditions of review for accepting proposals from outside the institution

The two institutions United Institute of Medical Sciences and the other institution (host and user) will enter into a MoU for utilizing the services of the EC of the host institution or the user institution should provide a 'No Objection Certificate' and agree to be overseen by the EC of the United Institute of Medical Sciences.

• The EC of the United Institute of Medical Sciences should have access to all research records including the source documents and research participants for continuing review of the implemented project, including site visits.

• The EC of the United Institute of Medical Sciences can undertake site monitoring and will have all the rights and responsibilities related to ethical review of the projects submitted by the user institutions.

12. Policy regarding training for new and existing committee members along with standard operating procedures

•At the time of constitution of the institutional ethics committee, latest approved SOPs will be circulated to all members of the IEC via e-mail and hardcopy as well. Members will be encouraged to familiarize themselves with the SOPs before attending the IEC meeting.

• The Chairperson and/or Member Secretary will conduct a presentation of the IEC SOPs in the first meeting of the newly constituted IEC.

• At the time of appointment or within the six months of appointment to the IEC, each member should have a valid GCP (Good Clinical Practice) certificate as a pre-requisite to induction in the IEC as GCP certificate is the universal standard in Clinical Research.

• The members will be required to update their GCP certification periodically.

• The IEC may also request a non-IEC member specialized in a topic of importance to impart training to the IEC members. The topics of training will be selected to help members understand their roles and responsibilities while reviewing the research protocols.

- The topics will also include, but are not limited to regulatory guidelines, advancements in health research that could impact review of research protocols, research ethics, and concept of fairness and equity in research participation, conflict of interest, Informed consent and its significance, privacy and confidentiality matters, etc.

- The IEC Secretariat will also maintain logs of the training and certificates attended by the IEC members.

- Chairperson, Member secretary and members will also be encouraged by the appointing authority to attend training in Research Ethics, Bioethics Conferences, Workshops, Seminars to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.

- The members should submit the certificates of such Ethics Conferences/Workshops/Seminars to the IEC Secretariat for IEC record.

13. 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 fulfil 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 than 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.

Annexure-2

DECLARATION OF CONFLICT OF INTEREST FORM

Investigator/Sponsor / CROProtocol No.:

Protocol Title:

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

14. 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

15. Commitments of the ethics committee:

1.The Committee shall review and accord its approval to a biomedical health research and also carry ongoing review of the projects at appropriate intervals, as per National Ethical Guidelines Biomedical and Health Research Involving Human Participants ICMR-2017 to safeguard the rights, safety and well- being of the trial subjects.

2. The Committee shall allow inspectors or officials authorized by the Department of Health Research (DHR) to enter its premises to inspect any record, data or any document related to research projects and provide adequate replies to any query by such inspectors or officials.

3.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).

16. Implementation and distribution of SOP:

The approved SOP will be implemented from the effective date and will be available on the Institutional website (https://www.unitedmedicity.com/). With the release of new version of SOP, the older one will no longer be effective.

17. Review & request for revision of the existing SOP:

1. Any member of IEC or Investigator of United Institute of Medical Sciences, who notices any inconsistency or has any suggestion on how to improve a procedure, should communicate through the Member Secretary/Chairman of the IEC, through provided email ID- iec@unitedmedicity.com

2. If IEC agree with the request then appropriate team will be designated by the Head of the institute and Chairman of IEC, United Institute of Medical Sciences, 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 amendments and record the date of review in the SOP master file.

18. 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 1st July 2023
2. International Conference on Harmonization, guidances on good clinical practice (ICHGCP) (1996). Available at https://www.ich.org/LOB/media!MEDIA482.pdf accessed on 1st July 2023
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 1st July 2023
4. Circulars. Available at: https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/ (Accessed: 11 September 2023).
5. Ethics Committee - Indian Association of Preventive & Social ... - IAPSM. (n.d.). http://iapsm.org/pdf/IAPSM-ethics-committee/eciapsm-sop-latest.pdf
6. Standard operating procedure (SOP) for Institutional Ethics Committee. (n.d.). https://aiimsbibinagar.edu.in/pdf/IEC/IEC%20SOP%20AIIMS%20BBN.pdf
7. Standard Operating Procedure Institutional Ethics Committee, NEIGRIHMS ... Available at: https://www.neigrihms.gov.in/Latest%20News/DDA/IEC-SOP_ver%202.1.pdf (Accessed: 08 September 2023).
8. Department of Health Research Ministry of Health & Family Welfare, Government of India National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) (no date) DHR. Available at: https://naitik.gov.in/DHR/Downloads (Accessed: 09 September 2023).

Annexure-3

INSTITUTIONAL ETHICS COMMITEE

United Institute of Medical Sciences

Project Submission Form

Version: 01

ECRef.No. *(For office use):*

Project Submission Checklist

1. Cover letter (To Member Secretary IEC)
2. Project submission form
3. Protocol (Complete research project)
4. Case record form & Informed consent form (Hindi and or English)
5. GCP certificate of Principal Investigator and Co-Investigators

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

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

1) Name of Principal Investigator:
.....

2) Department: .....

3) Date of submission: dd mm yy

4) Type of review requested : Expedited review ☐ Full committee review ☐

5) Title of the study:
.....

.....
.....

6) Protocol number: ..... Version number: .....

7) Details of Investigators:

Name	Qualification And Designation	Department and Institution	Contact details (mobile no. email id)
Principal Investigator/Guide			
Co-investigator/student/fellow			

*add more rows if required

8) Duration of the study: ……

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for project: …… ……

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

(Specify)……

SECTION B- RESEARCH RELATED INFORMATION

3. INTRODUCTION

(In terms of rationality and innovation involved in the project within 300 words):

……

……

……

……

……

……

……

……

4. AIMS/ OBJECTIVE

(Clearly state the aims or objectives of the study. Whenever possible this should be in the form of a hypothesis):

.....

.....

.....

5. OVERVIEW OF RESEARCH

(a) Lay summary (*Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.* within 300 words):

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

(b) Type of study:

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

Any others
(Specify).....

6. METHODOLOGY

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

Total Sample size (***n***): .....

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

(b) Justification for the sample size chosen (with formula): .....

.....

(c) Inclusion criteria:

.....

(d) Exclusion criteria:

.....

SECTION C: PARTICIPANT RELATED INFORMATION

7. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteers ☐ Patients ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)*

.....

Who will do the recruitment?

.....

(b) Participant recruitment method*(Specify)*

.....

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

ii. If yes, *(Specify)*: .....

iii. Provide justification for inclusion / exclusion: .....

.....

.....

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

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

.....

.....

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

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

.....

.....

8. 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 (*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 6 Table 2.1*)

Less than Minimal risk ☐ Minimal risk ☐

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

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

.....

.....

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

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

(c) Are adverse events expected in the study ? (*The term adverse events in this regard encompass both serious and non-serious adverse events*) Yes ☐ No ☐ NA ☐

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

If Yes, Specify .....

.....

.....

9. INFORMED CONSENT

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

.....

.....

(b) Who will obtain the informed consent?

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

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

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

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

.....

(d) Provide details of consent requirements for previously stored samples if used in the study *(as applicable)*

.....

.....

(e) 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)	☐				

.....

10. PAYMENT/COMPENSATION

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

PI ☐ Institution ☐ Sponsor ☐ N/A ☐

(specify).....

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

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

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

If yes, specify.

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

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

If yes, specify.....

(e) Is there a provision for ancillary care for unrelated illness during the study period? Yes ☐ No ☐ N/A ☐

If yes, please specify.....

11. STORAGE AND CONFIDENTIALITY

(f) Identifying Information: Study Involves samples/data. Yes ☐ No ☐ NA ☐

If Yes, 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: DECLARATION AND CHECKLIST

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

Name of PI: ..... Signature: .....

Name of Co-PI: ..... Signature:.....

Signature: .....Signature:.....

Name of Guide: .....

Signature: .....

Name of HOD: .....

13. CHECKLIST

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

MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee;

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

[1]*Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants*

Annexure-4

INFORMED CONSENT DOCUMENT

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. (xvi) Any other pertinent information.

Annexure-5

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:

Signatory's Name: _____ Date:___/_____/ ___

Study Investigator's Name: _____Sign:_____ Date:__/__/ __

Name of the Witness: _____Sign:_____Date:__/__/__

Annexure-6

Serious Adverse Event Reporting Format (Biomedical Health Research)

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. Participant details:

Initials/ID

Age at the time of event

Gender : Male/Female

Weight (Kgs) :

Height (cms) :

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

If yes, please provide details.

15. In caseofamulti-centricstudy,haveanyoftheotherstudysitesreportedsimilar SAEs ?

(Please list number of cases with details if available)

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

A. Expected event/ Unexpected event

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

17. In case of death, state probable cause of death.
18. No permanent/significant functional/cosmetic impairment □ 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

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

Signature of PI with date

Annexure-7

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 participant s 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) Report of DSMB Yes □ No □ NA

(d) Any other remark

(e) Have any participants withdrawn from this study since the last approval?

Yes □ No□ NA□ If yes, total number withdrawn and reasons:

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.9Yes □ No□

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

(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 t h e last review? Yes □ No□

Describe in brief:

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

13. Hastherebeenanyprotocoldeviations/violationsthatoccurredduringthisperiod?

If yes, number of deviations

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

If no, state reasons

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

15. Are there any publications or presentations during this period? Yes □ No□
If yes give details:……

Any other comments:

Signature of PI:

Annexure-8

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-9

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. 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?