	"INSTITUTIONAL ETHICS COMMITTEE" ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No. 1.2
Purpose	The "INSTITUTIONAL ETHICS COMMITTEE" AIIMS, Bathinda aims to ensure a competent review of scientific and ethical aspects of the projects/ research proposals including drug trials received. The committee shall safeguard the rights, safety, and well-being of all the trial subjects. Special attention shall be paid to trials that include vulnerable subjects and conduct ethical review in an emergency such as the one that occurred after the recent pandemic.	
Scope	The procedure covers a competent review of the research projects/ proposals in human subjects and/or patients (including medical education projects, STS projects, Human studies, file audit, Registries etc.).	
Preparation/Revision Date	7-9-2020, Revised 12-09-2023, Revised 04-08-2025	
Name of Ethics Committee	INSTITUTIONAL ETHICS COMMITTEE, AIIMS BATHINDA	
Address of Ethics committee	All India Institute of Medical Sciences, Bathinda; Jodhpur Romana, Mandi Dabwali Road, Bathinda, Punjab- 151001.	

	Name	Designation	Date/ Signature
Prepared by	Dr Priti Chaudhary & Dr. Jitender Aneja	Former and Present Member Secretaries respectively	7-9-2020; revised 12-09-2023, Revised 04-08-2025
Reviewed by	Dr. Joseph Mathew	Chairman, IEC	
		Also reviewed by all the Committee members, mentioned in the list.	
Authorized by	Dr. Meenu Singh	Executive Director& CEO	
Accepted by	Dr. Meenu Singh	Executive Director& CEO	

IEC, AIIMS, Bathinda		
Document No. 1	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: General Terms & References	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

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Title: Standard Operating Procedures for Establishing Institutional Ethics Committee of All India Institute of Medical Sciences (AIIMS), Bathinda

1. **Scope of the SOPs**

   These SOPs aim at providing the terms of reference for the constitution and selection of the IEC, AIIMS, Bathinda. These SOPs also describe the roles and responsibilities of the IEC, AIIMS, Bathinda, the procedures to be followed to ensure the confidentiality of all activities undertaken by IEC, AIIMS, Bathinda.

2. **Responsibility**

   The selection of Chairperson, member secretary and the IEC members will be done by the Head of the Institution (Executive Director, AIIMS, Bathinda). It is the responsibility of all IEC members and Secretariat to read, understand and follow this SOP.

3. Detailed instructions for the composition of the Institutional Ethics Committee, AIIMS, Bathinda

   a. The IEC shall be established by the Head of Institution i.e. Executive Director.

   b. The Convenor of the IEC may suggest the names of the potential members for the constitution of the IEC, but the final decision shall remain with the Head of Institution.

   c. IEC will be a multi-disciplinary body which shall comprise members from different sectors.

   d. It will comprise of a minimum of seven and a maximum of 15 members and preferably 50% of the members will be non-affiliated or from outside the institution.

   e. The IEC will have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

   f. The Head of Institution/Executive Director will select and nominate the

Chairperson and Member Secretary for the IEC. IEC will be constituted by the Director in consultation with the Chairperson. The Director will ensure that the IEC is established in accordance with the applicable rules and regulations and appropriate guidelines and in accordance with the values and principles of the communities they serve. The Director will designate and instruct the Chairperson of the IEC to conduct the regular proceedings of the IEC of AIIMS, Bathinda.

g. The IEC members will be a combination of medical and non-medical, scientific, and non-scientific persons including lay persons to represent the different points of views. They shall have different background to promote complete and adequate review of research. The members shall have the required qualifications as prescribed by the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (ICMR, 2017, 2018).

h. To maintain independence, the head of the institution will not be a part of the IEC but will act as an appellate authority to appoint the committee or to handle disputes.

i. The Chairperson and Member Secretary may have dual roles in the ethics committee. They may fulfil a role based on their qualifications (such as that of clinician, legal expert, basic scientist, social scientist, lay person etc.) in addition to taking on the role of Chairperson or Member Secretary.

j. The composition, affiliations, qualifications, member specific roles and responsibilities shall be as per the given Table-

Sr. No.	Member of IEC	Definition/description
1.	ChairpersonNon-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC	• Conduct EC meetings and be accountable for independent and efficient functioning of the committee • Ensure active participation of all

		members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations • Ratify minutes of the previous meetings • In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting. • 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
2.	**Member Secretary/ Alternate Member Secretary** (optional) Affiliated Qualifications – • Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills	• 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,

	• Should be able to devote adequate time to this activity which should be protected by the institution	communication and archiving • Ensure training of EC secretariat and EC members • Ensure SOPs are updated as and when required • Ensure 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.
3.	**Basic Medical Scientist(s)** Affiliated/ non-affiliated Qualifications – • Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report • For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

4.	**Clinician(s)** Affiliated/ non-affiliated Qualifications – • Should be individual/s with recognized medical qualification, expertise and training	• 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 (if applicable) and all other protocol details and submitted documents.
5.	**Legal expert/s** Affiliated/ non-affiliated Qualifications - • Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law	• Ethical review of the proposal, Informed Consent Document (ICD) along with translations, Memorandum of Understanding (MoU), Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration,

		compliance with guidelines etc. • Interpret and inform EC members about new regulations if any
6.	**Social scientist/ philosopher/ ethicist/theologian** Affiliated/ non-affiliated Qualifications – • Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. 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.
7.	**Lay person(s)** **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 • Desirable: 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.

4. Quorum Requirements for the IEC meetings
    a. A minimum of five members shall be present in the IEC meeting called in order.
    b. The quorum shall include both medical, non-medical or technical or/and non-technical members.
    c. Minimum one non-affiliated member shall be present to fulfil the quorum.

d. Preferably the lay person shall also be part of the quorum.

e. The quorum for reviewing regulatory clinical trials shall be in accordance with current CDSCO requirements. A Clinical Pharmacologist shall be present to complete the quorum while reviewing a clinical trial.

f. No decision shall be valid without fulfilment of the quorum.

5. The EC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.
6. The EC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.
7. The EC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power.
8. The Institutional Research Committee (IRC) will a priori review the proposals before these are submitted to the IEC. The IEC, however, can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.
9. **Terms of Reference for IEC members**

a. The Head of Institution will appoint all IEC members, including the Chairperson.

b. The appointment letter issued to all members shall specify the TORs. The letter issued by the head of the institution should include, at the minimum, the following: •

i. Role and responsibility of the member in the committee

ii. Duration of appointment

iii. Conditions of appointment

c. The term of IEC membership will be 3 years, extendable for one more term.

d. At the end of 3 years, the IEC may be reconstituted and 30-50% of the members may be replaced.

e. The IEC members (non-affiliated) will be given a reasonable honorarium for attendance at the meeting as decided by the Head of Institution.

f. The IEC members will be required to fulfil the following requirements of the IEC-

i. provide a recent signed CV and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;

ii. either be trained in human research protection and/or GCP at the time of induction into the EC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy)

iii. be willing to undergo training or update their skills/knowledge during their tenure as an EC member

iv. be aware of relevant guidelines and regulations

v. read, understand, accept and follow the COI policy of the EC and declare it, if applicable, at the appropriate time

vi. sign a confidentiality and conflict of interest agreement/s

vii. be willing to place her/his full name, profession and affiliation to the EC in the public domain

viii. be committed and understanding to the need for research and for imparting protection to research participants in research

10. Training of the IEC Members

a. Members of the IEC will be trained in human research protection, IEC functions and SOPs. The shall be conversant with ethical guidelines, GCP guidelines (if applicable) and relevant regulations of the country.
b. IEC members shall undergo initial and continuing training in human research protection, applicable IEC SOPs and related regulatory requirements. All trainings will be documented.
c. Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.
d. The IEC members shall be aware of local, social and cultural norms and emerging ethical issues.

11. Roles and responsibilities of the IEC

a. The basic responsibility of IEC is to ensure protection of the dignity, rights, safety and well-being of the research participants.
b. The IEC will ensure ethical conduct of research by the investigator team.
c. The IEC will be responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
d. The IEC will perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
e. The IEC will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
f. The IEC will assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.

g. The IEC Secretariat shall support the Member Secretary and Alternate Member Secretary (when appointed) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.

h. The IEC will ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.

i. The IEC will review the progress reports, final reports and AE/SAE and give needful suggestions regarding care of the participants and risk minimization procedures, if applicable.

j. The IEC will recommend appropriate compensation for research related injury, wherever required.

k. The IEC will carry out monitoring visits at study sites as and when needed.

l. The IEC will participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.

m. The IEC may see that conduct of same/similar research by different investigators from same institution is harmonized. 'Me too' research (replicative) will not to be encouraged and submission of same research to different funding agencies should not be accepted.

12. Submission and review procedures

a. The researchers shall submit research proposals as soft or hard copies, both duly signed and stamped by all the investigators, to the Secretariat for review in the prescribed format and required documents as per IEC SOPs (Annexure 1 & 2).

b. Types of Review

i. Exemption from review: Proposals with less than minimal risk where there are no linked identifiers, for example-

- Research conducted on data available in the public domain for systematic reviews or meta-analysis.

- Observation of public behavior when information is recorded without any linked identifiers and the observations/findings, and/or their disclosure would not harm the interests of the observed person(s).
- Quality control and quality assurance audits in the institution.
- Comparison of instructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

ii. Expedited review: Proposals that pose no more than minimal risk may undergo expedited review, for e.g.

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks, and left-over clinical samples.
- Research involving clinical documentation materials that are non-identifiable (data, documents, records).
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviation from originally approved research causing no risk or minimal risk.
- Progress/annual reports where there is no additional risk, for eg. Activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee.

- For multicenter research where a designated main EC among the participating sites has reviewed and approved the study, a local IEC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters.

iii. Full committee review: All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review for example-

- Research involving vulnerable populations, even if the risk is minimal.
- Research with minor increase over minimal risk (**Refer to the Table below**).

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, urine samples etc.
Minor increase over minimal 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.

- Studies involving deception of participants (Refer to the Section 5.11 and Box 5.1 of "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants" ICMR National Ethical Guidelines, 2017 for the details).
- Research proposals that have received exemption from review or have undergone expedited review/undergone subcommittee review shall be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.
- Major deviations and violations in the protocol.

- 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.
- 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.
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

c. The Member Secretary/Secretariat will 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. A researcher cannot decide that her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the EC. The decision on the type of review required rests with the EC and will be decided on a case-to-case basis. Researchers can approach the EC with appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

e. Expedited review can be conducted by Chairperson, Member Secretary and one or two designated members or as specified in SOPs.

f. Approval granted through expedited review and the decisions of the SAE subcommittee must be ratified at the next full committee meeting.

g. IEC members will be given enough time (at least 1 week) to review the proposal and related documents, except in the case of expedited review.

h. All IEC members will be expected to review all proposals. However, to better streamline the process of the review of proposals, the IRC shall coordinate with the IEC to submit the peer-reviewed proposals.

i. The IEC, AIIMS, Bathinda shall appoint at least a primary and secondary reviewer for each submitted proposal. The Member Secretary shall identify the primary and secondary reviewers for reviewing the scientific content and the ethical aspects in the proposal as well as the informed consent document, depending upon their individual expertise.

j. The Member Secretary may identify additional subject experts to review the proposal as per need. These experts may be invited to the IEC meeting or join via video/tele conference but will not participate in final decision making.

k. The IEC shall meet (at least) once in three months. However, in view of submission of a significant number of projects and to assist the researcher especially the MBBS students and post-graduate students, the IEC meeting may be convened to reduce the turnaround time.

l. The designated (primary and secondary) reviewers and subject expert shall conduct the initial review of the study protocol and study related documents as per the pre- defined study assessment form (Annexure-3).

m. The researcher will be called in to present a proposal or provide clarifications on the study protocol that has been submitted for review but should not be present at the time of decision making.

n. The primary and secondary reviewers will brief the members about the study proposal and review carried out as per IEC SOPs.

o. The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be recorded.

p. Representative(s) of the study group population can be invited during deliberations to offer their viewpoint but should not participate in the decision-making process.

q. The IEC may utilize electronic methods such as video/conference calls for connecting with other subject experts/independent consultants during the meeting.

r. All members of the EC (including the Chairperson and the Member Secretary) present in the room have the right to vote/express their decision and shall exercise this right.

s. The decision will be taken either by a broad consensus or majority vote (as per SOP) and will be recorded. Any negative opinion should be recorded with reasons.

t. The decisions may be recorded as Approved (with or without suggestions/comments), Revision with minor modifications/amendments (approval will be after examination by the Member Secretary or expedited review, as the case may be), Revision with Major modifications for resubmission (will be placed before the full committee for reconsideration for approval) or Not Approved (or termination/revoking of permission if applicable; clearly defined reasons will be given for not approving/terminating/revoking of permission).

u. Approval may be granted for the entire duration of the proposed research or can be subject to annual review depending on the type of study. The IEC shall review the annual report (counted from the day of approval or date of actual start of the study) for continuation as per SOP.

v. Depending on the risk involved, the progress of the proposal may be monitored annually or at shorter intervals (quarterly, half yearly) as per IEC decision. Approval may be continued if progress is satisfactory.

w. An IEC may decide to reverse its approval of a study if it receives information that may adversely affect the benefit-risk assessment.

x. The Member Secretary (assisted by the Secretariat) will record the discussions and prepare the minutes which should be circulated to all the members for comments before final approval by the Chairperson/Vice-Chairperson/designated member of the committee.

y. The decision of the IEC will be communicated to the researcher along with suggestions, if any.

z. The researcher will have an opportunity to reply/clarify to IEC comments or to discuss or present her/his stand.

aa. The researcher can also approach the Head of the Institute who serves as an appellate for EC matters.

bb. The Head of the Institute as appellate has the power to dissolve the IEC or reappoint an IEC.

13. Review of multicentric research

a. Multicentre research is conducted at more than one centre by different researchers usually following a common protocol. A large number of clinical trials, clinical studies and public health research including surveys are conducted at several research centres within the country or at international sites. Multicentric research studies are carried out with the primary aim of providing a sound basis for the subsequent generalization of its results. All sites are required to obtain approval from their respective I/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. There are concerns, however, related to duplication of effort in the parallel review by the involved I/ECs, wastage of time and also those related to communication between the committees. Therefore, in multicentric studies using a common protocol the considerations mentioned in below sections may be made.

i. Separate review by IECs of all participating sites:

- The IEC/Secretariats of all the participating sites shall establish communication with one another.
- If any IEC does not grant approval for a study at a site the reasons must be shared with other IECs and deliberated upon.
- The IEC 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.

ii. Common review for all participating sites in multicentric research

- In order to save time, prevent duplication of effort and streamline the review process, the IEC can decide to have one designated main IEC, the decisions of which may be acceptable to other I/ECs. This is especially important for 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 meeting of the designated main IEC can be attended by nominated members of IECs of the participating centres to discuss their concerns, if any, about ethics or human rights and to seek solutions and communicate the decision of the main IEC to their respective IECs.
- This IEC should be located in India and registered with the relevant authority (if applicable).

- Meetings should be organized at the initial and, if required, intermediary stages of the study to ensure uniform procedures at all centres.
- The site IECs, however, retain their rights to review any additional site specific requirements, ensure need-based protection of participants or make changes in the informed consent document (ICD), translations and monitoring research as per local requirements.
- The protocol may be modified to suit local requirements and should be followed after it is duly approved by the IEC of the host institutes/decision of main IEC is accepted.
- Adherence to protocols, including measures to terminate the participation of the erring local centres, if required should be monitored.
- The common review is applicable only for IECs in India. In case of international collaboration for research and approval by a foreign institution, etc., the local participating sites would be required to obtain local ethical approval.
- Sponsor/funding agencies should be informed about any site-specific changes being made by the authors, and the modified version should only be used by the concerned site.
- Plans for manuscript publication and a common final report with contributors from the participating sites should be decided upon before initiation of the study.
- Site-specific data may be published only after the appropriate authorities accept the combined report and appropriate permissions are obtained.

14. Continuing Review

a. Ongoing research shall be reviewed at regular intervals, at least once a year, (or more often, if deemed necessary depending on the level of risk).

b. The IEC shall continually evaluate progress of ongoing proposals, review SAE reports from all sites along with protocol deviations/violations and non-compliance, any new information pertaining to the research and assess final reports of all research activities.

c. Clinical trials under the purview of a licensing authority must comply with all regulations applicable to SAEs. The IEC will also ensure compliance by the researcher. The SOPs pertaining to Clinical Trials may be utilized for this purpose.

15. Record Keeping

a. All documentation and communication of IEC should be dated, filed and preserved according to written procedures.

b. Confidentiality will be maintained during access and retrieval procedures by designated persons.

c. All active and inactive (closed) files will be appropriately labelled and archived separately in designated areas.

d. Records will be preferably maintained in soft copies, but hard copies, when required will be kept too.

e. All records will be archived for a period of at least 3 years after the completion/ termination of the study.

f. Documents related to regulatory clinical trials will be archived for 5 years after the completion/termination of the study or as per regulations.

g. Records will be archived for a longer period, if required by the sponsors/regulatory bodies.

h. IEC will describe archival and retrieval mechanisms in SOPs.

i. IEC records will be accessible for inspection by authorized representatives of regulatory agencies.

16. Registration and accreditation of IEC, AIIMS, Bathinda

a. The IEC will ensure that processes are in place to safeguard the quality of ethical review as well as compliance with national/international and applicable regulations.
b. The IEC, AIIMS, Bathinda shall register with the relevant authority as per the regulatory requirements.
c. Efforts will be made to seek recognition/certification/accreditation from recognized national/international bodies such as Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Association for the Accreditation of Human Research Protection Programmes (AAHRPP), CDSCO and Quality Council of India through National Accreditation Board for Hospitals and Healthcare Providers (NABH) or any other.

Annexures:

IEC/AIIMS/BTI/SOP/TOR/Annex 1: Details of documents to be submitted to the IEC for review of research project.

IEC/AIIMS/BTI/SOP/TOR/Annex 2: Details of documents to be included in the protocol.

IEC/AIIMS/BTI/SOP/TOR/Annex3: Details of Ethical Issues related to reviewing a protocol.

IEC/AIIMS/BTI/SOP/TOR/Annex 1:

Details of documents to be submitted to the IEC for review of research project

Sr. No.	Name of Document
1.	Cover letter to the Member Secretary
2.	Type of review requested (with appropriate proforma)
3.	Application form for initial review
4.	The correct version of the informed consent document (ICD) in English and the local language(s). Translation and back translation certificates (if applicable)
5.	Case record form/questionnaire
6.	Recruitment procedures: advertisement, notices (if applicable)
7.	Patient instruction card, diary, etc. (if applicable)
8.	Investigator's brochure (as applicable for drug/biologicals/device trials)
9.	Details of funding agency/sponsor and fund allocation (if applicable)
10.	Brief curriculum vitae of all the study researchers
11.	A statement on COI, if any
12.	GCP training certificate (preferably within 5 years) of investigators (clinical trials)
13.	Any other research ethics/other training evidence, if applicable as per EC SOP
14.	List of ongoing research studies undertaken by the principal investigator (if applicable)
15.	Undertaking with signatures of investigators
16.	Regulatory permissions (as applicable)
17.	Relevant administrative approvals (such as HMSC approval for International trials)
18.	Institutional Committee for Stem Cell Research (IC-SCR) approval (if applicable)
19.	MoU in case of studies involving collaboration with other institutions (if applicable)
20.	Clinical trial agreement between the sponsors, investigator and the head of the institution(s) (if applicable)
21.	Documentation of clinical trial registration (preferable)
22.	Insurance policy (it is preferable to have the policy and not only the insurance certificate)for study participants indicating conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
23.	Indemnity policy, clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage of risk (if applicable)
24.	Any additional document(s), as required by EC (such as other EC clearances for multicentric studies)
25.	Protocol

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IEC/AIIMS/BTI/SOP/TOR/Annex 2:

Details of documents to be included in the protocol

Sr. No.	Name of Document
1.	The face page carrying the title of the proposal with signatures of the investigators
2.	Brief summary/ lay summary
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 (if applicable)
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 placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld, justification for the same
10.	Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. AV recording if applicable; informed consent for stored samples
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
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
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

Details of Ethical Issues related to reviewing a protocol

1.	**Social Values**	The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and ECs must ensure that the planned research has social value.
2.	**Scientific design and conduct of the study**	• Valid scientific methods are essential to make the research ethically viable as poor science can expose research participants or communities to risks without any possibility of benefit. • Although IECs may obtain documentation from a prior scientific review, they should also determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy. • The IEC can raise scientific concerns (even if the study has prior approval of a scientific committee) if it may affect quality of research and or safety of research participants.
3.	**Benefit-risk assessment**	• The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research. • Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole. • The IEC shall review plans for risk management, including withdrawal criteria with rescue medication or procedures. • The IEC shall give advice regarding minimization of risk/ discomfort wherever applicable.

		• Adequate provisions will be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)
4.	**Selection of the study population and recruitment of research participants**	• Recruitment shall be voluntary and non-coercive. Participants should be fairly selected as per inclusion and exclusion criteria. However, selection of participants shall be distributive such that a particular population or tribe or economic group is not coerced to participate or benefit. • Participants shall be able to opt out at any time without their routine care being affected. • No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits. • Vulnerable groups may be recruited after proper justification is provided.
5.	**Payment for participation**	• Plans for payment for participation, reimbursement of incurred costs, such as travel or lost wages, incidental expenses and other inconveniences should be reviewed. • There is a need to determine that payments are not so large as to encourage prospective participants to participate in the research without due consideration of the risks or against their better judgement. No undue inducement must be offered.
6.	**Protection of research participants' privacy and confidentiality**	• The IEC shall examine the processes that are put in place to safeguard participants' privacy and confidentiality. • Research records to be filed separately than routine clinical records such as in a hospital setting.
7.	**Community considerations**	• The IEC shall ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs. • The proposed research shall not lead to any stigma or discrimination. Harm, if any, should be minimized.

		• Plans for communication of results to the community at the end of the study should be carefully reviewed. • It is important to examine how the benefits of the research will be disseminated to the community.
8.	**Qualifications of researchers and adequacy assessment of study sites**	• The IEC shall look at the suitability of qualifications and experience of the PI to conduct the proposed research along with adequacy of site facilities for participants.
9.	**Disclosure or declaration of potential COI**	• The IEC shall review any declaration of COI by a researcher and suggest ways to manage these. • The IEC shall manage COI within the EC and members with COI should leave the room at the time of decision making in a particular study.
10.	**Plans for medical management and compensation for study related injury**	• The proposed plan for tackling any medical injuries or emergencies should be reviewed. • Source and means for compensation for study related injury should be ascertained.
11.	**Review of the informed consent process**	The informed consent process must be reviewed keeping in mind the following: • the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations; • the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs

IEC, AIIMS, Bathinda		
Document No. 1	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: General Terms & References	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

Josephlmathew

	"INSTITUTIONAL ETHICS COMMITTEE" ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No. 2.2
Purpose	The "INSTITUTIONAL ETHICS COMMITTEE" AIIMS, Bathinda aims to ensure a competent review of scientific and ethical aspects of the projects/ research proposals including drug trials received. The committee shall safeguard the rights, safety, and well-being of all the trial subjects. Special attention shall be paid to trials that include vulnerable subjects and conduct ethical review in an emergency such as the one that occurred after the recent pandemic.	
Scope	The procedure covers a competent review of the research projects/ proposals in human subjects and/or patients (including medical education projects, STS projects, Human studies, file audit, Registries etc.).	
Preparation/Revision Date	7-9-2020, Revised 12-09-2023, Revised 04-08-2025	
Name of Ethics Committee	INSTITUTIONAL ETHICS COMMITTEE, AIIMS BATHINDA	
Address of Ethics committee	All India Institute of Medical Sciences, Bathinda; Jodhpur Romana, Mandi Dabwali Road, Bathinda, Punjab- 151001.	

Approvals

	Name	**Designation**	**Date/ Signature**
Prepared by	Dr Priti Chaudhary & Dr. Jitender Aneja	Former and Present Member Secretaries respectively	7-9-2020; revised 12-09-2023, Revised 04-08-2025
Reviewed by	Dr. Joseph Mathew	Chairman, IEC	
		Also reviewed by all the Committee members, mentioned in the list.	
Authorized by	Dr. Meenu Singh	Executive Director& CEO	
Accepted by	Dr. Meenu Singh	Executive Director& CEO	

IEC, AIIMS, Bathinda		
Document No. 2	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

Josephlmathew

Meenu Singh

Title: Standard Operating Procedures (SOPs) for research projects involving vulnerable populations.

1. **Purpose of these SOPs-** To define the vulnerable populations and lay down procedures to deal with research projects involving vulnerable populations.
2. **Scope:** These SOPs shall apply to research being conducted on vulnerable populations.
3. **Definition of Vulnerable Population**: As per the ICMR guidelines 2017-

   Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons.

   Individuals are considered to be vulnerable if they are:

   1. Socially, economically, or politically disadvantaged and susceptible to exploitation
   2. Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
   3. Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions.
   4. 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.
4. **Responsibility of the IEC:**

   a. To ensure that the researcher/s must justify the inclusion/exclusion of a vulnerable population.

b. The IEC may invite a community representative to EC meetings to make sure the research is responsive to their needs and the informed consent process is appropriate.

c. Additional precautions will be taken by all stakeholders such as researchers, ECs and sponsors to avoid exploitation of vulnerable participants.

d. Informed consent process will be well documented and additional measures adopted if required, such as audio-visual/audio recording of assent/consent/reconsent.

e. Research proposals shall undergo review in a full committee meeting.

f. Protection of privacy and dignity as well as provision of quality health care will be ensured in dealing with vulnerable people, especially the minorities.

g. Research involving children, in addition, should follow the National Ethical Guidelines for Biomedical Research Involving Children, ICMR, 2017.

h. Due approvals from competent authorities before entering tribal areas will be sought.

i. Research involving cognitively impaired individuals or those with mental illness will be done carefully, especially if there is risk to themselves, to others or suicidal ideation.

j. The IEC shall carry out the benefit–risk analysis and examine risk minimization strategies.

Annexures: The following annexures (adapted from IEC/PGIMER/Chandigarh) shall apply to certain groups of vulnerable population and must be filled in complete by the principal investigator and shall be reviewed by the IEC.

Annexure 1: IEC/AIIMS/BTI/SOP/VP/ANNEX14- CHECKLIST- Requirements for research involving children.
Annexure 2: IEC/AIIMS/BTI/SOP/VP/ANNEX15- Checklist- Requirements for research involving pregnant women and foetuses.

Annexure 3: IEC/AIIMS/BTI/SOP/VP/ANNEX16- Checklist- Requirements for research involving cognitively impaired adults.
Annexure 4: IEC/AIIMS/BTI/SOP/VP/ANNEX17- Checklist- Requirements for research involving students, employees, or interns/junior/senior residents.
Annexure 5: IEC/AIIMS/BTI/SOP/VP/ANNEX18- Checklist- Requirements for genetic research.

Annexure 1: IEC/AIIMS/BTI/SOP/VP/ANNEX14-
CHECKLIST- Requirements for research involving children.

Name of Principal Investigator:

Study Title:

S. No.	Questions	Yes	No	NA
1.	Does the research pose greater than minimal risk to the children?			
2.	If yes: Are convincing scientific and ethical justifications given?			
3.	If yes: Are adequate safeguards in place to minimize these risks?			
4.	Does the study involve healthy children?			
5.	If yes: Is the inclusion of healthy children justified?			
6.	Are the studies conducted on animals and adults appropriate and justified?			
7.	If **No:** Is the lack of studies conducted on animals and adults justified?			
8.	Will older children be enrolled before younger ones?			
9.	Is permission of both parents necessary?			

10.	If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
11.	If Yes: Are the conditions acceptable?			
12.	Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and/or unrealistic promises?			

13.	Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
14.	Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?			
15.	Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
16.	Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
17.	Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
18.	Does the research involve possibility of findings which may have implications for other family members? (for e.g. genetic risk, HIV infection, Hepatitis C}			
19.	If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
20.	Are parents required to be present during the conduct of the research? (Are proposed participants' very young?)			

Signature of Principal Investigator: _____

Date:

Comments of Primary Reviewer:

_____

_____

IEC, AIIMS, Bathinda		
Document No. 2	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

Annexure 2: IEC/AIIMS/BTI/SOP/VP/ANNEX15-
Checklist- Requirements for research involving pregnant women and/or foetuses prior to delivery.

Name of Principal Investigator:

Study Title:

Sr. No.	Questions	Yes	No	NA
Section A	**This research involves pregnant women or fetuses prior to delivery**			
1.	Where scientifically appropriate preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women have been conducted and provide data for assessing potential risks to pregnant women and fetuses?			
2.	Where The risk to the fetus not greater than minimal, or any risk to the fetus, which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
3.	Any risk that is least possible for achieving the objectives of the research?			
4.	Where the woman's consent or the consent of her legally authorized representative obtained in accordance with the informed consent provisions, unless altered or waived.			
5.	Where the woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child?			

6.	Where no inducements, monetary or otherwise, be offered to terminate a pregnancy?			
7.	The decision of investigator determining the viability of a fetus will not have an effect if the woman participates in the research.			

If the response to any of the above is NO, the research should not be approved by IEC.

Signature of Principal Investigator: Date:

IEC Office use only

Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

Section B: This research involves fetuses after delivery

Sr. No.	**Questions/** Queries	Yes	**No**	**NA**
1.	Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
2.	Where the individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus.			
3.	No inducements, monetary or otherwise will be offere to terminate a pregnancy?			
4.	Women's participation in the research will not influence the decisions by investigator with respect to the timing, method or procedures used to terminate pregnancy; and			
5.	The decision of investigator determining the viability of a fetus will not have an effect if the woman participates in the research			
	AND			
6.	**Fetuses of uncertain viability-**			
6a	A. Does the research hold out the prospect of enhancing the probability of survival of the fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research;			
	OR			
	The purpose of the research is development of important biomedical knowledge which cannot be obtained by other means and there will be nor risk to the fetus resulting from the research.			

	B. The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained?			

7.	**In research involving non-viable fetuses**			
7a	Vital functions of the fetus will not be artificially maintained;			
7b	There will be no risk to the fetus resulting from the research;			
7c	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
7d	The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteranate provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. (The consent of a legally authorized representative of either or both parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.)			

If the response to any of above is **NO,** the research should not be approved by IEC.

<u>This type of research can be conducted only after IEC finds that</u>

A. The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women and/or fetuses.

B. The research will be conducted in accordance with applicable regulatory and ethical guidelines.

Signature of Principal Investigator: Date:

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

Annexure 3: IEC/AIIMS/BTI/SOP/VP/ANNEX16-
Checklist- Requirements for research involving cognitively impaired adults.

Name of Principal Investigator:

Study Title:

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the participant** (All items must be "Yes")

Sr. No.	Item	Yes	No
1.	Is the recruitment of participants justified considering rationale and objectives of study?		
2.	Is the risk justified by anticipated benefit to the participants?		
3.	The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches?		
4.	Will the participants be withdrawn if they appear to be unduly distressed?		
5.	The proposed plan for the assessment of the capacity to consent is adequate.		
6.	Assent is required of: (One of the following must be "Yes" A. All participants B. All participants capable of being consulted C. None of the participant		
7.	The consent document includes a signature line for a legally authorized representative.		

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the participant (All items must be "Yes")

Sr. No.	Item	Yes	No
8.	Is the recruitment of participants justified considering the rationale and objectives of study?		
9.	Are the foreseeable risks to the participants low?		
10.	Is the negative impact on the participant's well-being minimized and low?		
11.	Will the participants be particularly closely monitored?		
12.	Will the participants be withdrawn if they appear to be unduly distressed?		
13.	The proposed plan for the assessment of the capacity to consent is adequate.		
14.	Assent is required of: (One of the following must be "Yes" A. All participants B. All participants capable of being consulted C. None of the participant		
15.	The consent document includes a signature line for a legally authorized representative.		

Signature of Principal Investigator: Date:

IEC Office use only

Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

Annexure 4: IEC/AIIMS/BTI/SOP/VP/ANNEX17-
Checklist- Requirements for research involving students, employees, or interns/junior/senior residents working in AIIMS, Bathinda.

Name of Principal Investigator:

Study Title:

Research involving participants who are students, employees or residents of AIIMS, Bathinda, require special considerations (All items must be "Yes")

Sr. No.	Items	Yes	No
1.	Have the participants been assured that their status (education, employment and/or promotion) will not be affected by any decision to participate or not?		
2.	Have the risks to participants been minimized?		
3.	Have the participants been assured that their participation is voluntary (no signs of coercion)?		
4.	Have the participants been assured that privacy and confidentiality will be protected?		

Signature of Principal Investigator: Date:

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

IEC, AIIMS, Bathinda		
Document No. 2	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

Annexure 5: IEC/AIIMS/BTI/SOP/VP/ANNEX18-
Checklist- Requirements for genetic research.

Name of Principal Investigator:

Study Title:

Considerations for genetic research (All items must be "Yes")

Sr. No.	Items	Yes	No
1.	Will samples be made anonymous to maintain confidentiality? If yes, then the following checklist points are not applicable.		
2.	Will the results of individual participants be disclosed to the patient? If yes, a. Has the the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result? b. Will the results be used in management of current condition of patient?		
3.	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
4.	Does the proposed study population comprise family members?		
5.	Will family members be implicated in the studies without consent?		
6.	Will the samples be destroyed in the future?		
7.	Is genetic counselling being offered?		

Signature of Principal Investigator: Date:

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Comments of Primary Reviewer:

Primary Reviewer's Signature and Date:

IEC, AIIMS, Bathinda		
Document No. 2	Document Type: SOP	Version: 2
Prepared by: Dr. Jitender Aneja	Section: Vulnerable Populations	
Revision No: 1	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		

Josephlmathew

	"INSTITUTIONAL ETHICS COMMITTEE" ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No. 3.3
Purpose	The "INSTITUTIONAL ETHICS COMMITTEE" AIIMS, Bathinda aims to ensure a competent review of scientific and ethical aspects of the projects/ research proposals including drug trials received. The committee shall safeguard the rights, safety, and well-being of all the trial subjects. Special attention shall be paid to trials that include vulnerable subjects and conduct ethical review in an emergency such as the one that occurred after the recent pandemic.	
Scope	The procedure covers a competent review of the research projects/ proposals in human subjects and/or patients (including medical education projects, STS projects, Human studies, file audit, Registries etc.).	
Preparation/Revision Date	7-9-2020, Revised 12-09-2023, Revised 04-08-2025	
Name of Ethics Committee	INSTITUTIONAL ETHICS COMMITTEE, AIIMS BATHINDA	
Address of Ethics committee	All India Institute of Medical Sciences, Bathinda; Jodhpur Romana, Mandi Dabwali Road, Bathinda, Punjab- 151001.	

Approvals

	Name	**Designation**	**Date/Signature**
Prepared by	Dr Priti Chaudhary & Dr. Jitender Aneja	Former and Present Member Secretaries respectively	7-9-2020; revised 12-09-2023, Revised 04-08-2025
Reviewed by	Dr. Joseph Mathew	Chairman, IEC	
		Also reviewed by all the Committee members, mentioned in the list.	
Authorized by	Dr. Meenu Singh	Executive Director & CEO	
Accepted by	Dr. Meenu Singh	Executive Director& CEO	

Josephlmathew

IEC, AIIMS, Bathinda		
Document No.-3	Document Type: SOP	Version: 3
Prepared by: Dr. Priti Chaudhary	Section: Clinical Trials	
Revision No: 3	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		
Reference: National Ethical Guidelines for Biomedical and health research Involving Human Participants. Indian Council of Medical Research, 2017 and New Drugs & Clinical Trial Rules, 2019.		

Josephlmathew

Abbreviations

- **ADR** **Adverse Drug Reaction**
- **AE** **Adverse Event**
- **BA** **Bioavailability**
- **BE** **Bioequivalence**
- **CDSCO** **Central Drug Standard Control Organization**
- **CFR** **Code of federal Regulation**
- **CRF** **Case Record Form**
- **CTA** **Clinical Trial Agreement**
- **CV** **Curriculum Vitae**
- **DTEC** **Drug Trial Ethics Committee**
- **DCGI** **Drug Controller General of India**
- **DCR** **Drug and Cosmetic Rules**
- **DGFT** **Director General of Foreign Trade**
- **EC** **Ethics Committee**
- **GCP** **Good Clinical Practices**
- **GOI** **Government of India**
- **IB** **Investigator Brochure**
- **ICF** **Informed consent form**
- **ICH-GCP** **International Committee for Harmonization-Good Clinical Practices**
- **ICMR** **Indian Council of Medical Research**
- **IEC** **Institutional Ethics Committee**
- **PI** **Principal Investigator**
- **RCT** **Randomized Controlled Trial**
- **SAE** **Serious Adverse Event**
- **SOP** **Standard Operating Procedure**
- **WHO** **World Health Organization**

Definitions:

- **Standard Operating Procedure (SOP):** Detailed written instructions to achieve uniformity ofthe performance of a specific function.
- **Good Clinical Practices (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinicaltrials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

- **Clinical Trial:**
  Clinical trial in relation to a new drug or investigational new drug means, any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying it
  (i) Clinical or
  (ii) Pharmacological, including pharmacodynamics, pharmacokinetics or
  (iii) Adverse effects
  with the objective of determining the safety, efficacy or tolerance of such new drug or investigational n drug.

  Clinical Trial/study: Any investigation in human subjects intended to discover or verify the clinical pharmacological and other pharmacodynamic effect of an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous. Clinical Trials covered under various phases:

  - **Phase I**: Researchers test a new drug or treatment in a small group of people for the first time t evaluate its safety, determine a safe dosage range, and identify adverse effects.
  - **Phase II**: The drug or treatment is given to a larger group of people to further evaluate its safety
  - **Phase III**: The drug or treatment is given to large groups of people to confirm its effectiveness monitor adverse effects, compare it to commonly used treatments, and collect information tha will allow the drug or treatment to be used safely.
  - **Phase IV**: Studies are done after the drug or treatment has been marketed to gather informatio on the drug's effect in various populations and any adverse effects associated with long term us

IEC, AIIMS, Bathinda		
Document No.-3	Document Type: SOP	Version: 3
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Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		
Reference: National Ethical Guidelines for Biomedical and health research Involving Human Participants. Indian Council of Medical Research, 2017 and New Drugs & Clinical Trial Rules, 2019.		

- **Orphan Drug**
  Orphan drug means a drug intended to treat a condition which affects **not more than five lakh perso in India**.

- "**Post-trial access**" means making a new drug or investigational new drug available to a trial subject a completion of clinical trial through which the said drug has been found beneficial to a trial subject duri clinical trial, for such period as considered necessary by the investigator and the Ethics Committee.

IEC, AIIMS, Bathinda		
Document No.-3	Document Type: SOP	Version: 3
Prepared by: Dr. Priti Chaudhary	Section: Clinical Trials	
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Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		
Reference: National Ethical Guidelines for Biomedical and health research Involving Human Participants. Indian Council of Medical Research, 2017 and New Drugs & Clinical Trial Rules, 2019.		

- **New Drug**
  i. a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and th rules made thereunder, as per conditions specified in the labelling thereof and has **not been approved** safe and efficacious by the Central Licensing Authority with respect to its claims; or

  ii. a drug **approved** by the Central Licensing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

  iii. a fixed dose combination of two or more drugs, approved separately for certain claims and propose be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administratior dosage and dosage form; or

  iv. a modified or sustained release form of a drug or novel drug delivery system of any drug approved b the Central Licensing Authority; or

  v. a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to b used as drug.

- **Protocol**: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the International Conference on Harmonization Good Clinical Practice Guidelines the term protocol refers to protocol and protocol's amendments.

- **Protocol Amendment**: A written description of a change(s) to or formal clarification of a protocol.

- **Investigator Brochure (IB)**: A compilation of the clinical and nonclinical data on the investigational products which is relevant to the study of the investigational product(s) in human subjects.

- **Case Report form (CRF):** A printed, optical, or electronic document designed to record all the required information to be reported on each trial subject.

- **Informed Consent:** A process by which a subject, voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to

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Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		
Reference: National Ethical Guidelines for Biomedical and health research Involving Human Participants. Indian Council of Medical Research, 2017 and New Drugs & Clinical Trial Rules, 2019.		

the subject's decision to participate along with the signatures of his/her nominee. Informed consent is documented by means of a written, signed and dated informed consent form also showing the name of nominees and their signatures.

- **Adverse event (AE):** Any unfavorable and unintended sign (including an abnormal laboratory finding symptom, or disease temporally associated with the use of a medicinal (investigational) product, whethe related to the medicinal/investigational product.
- **Adverse Drug Reaction (ADR):** All noxious and unintended response to a medicinal product related to any dose should be considered adverse drug reactions.

IEC, AIIMS, Bathinda		
Document No.-3	Document Type: SOP	Version: 3
Prepared by: Dr. Priti Chaudhary	Section: Clinical Trials	
Revision No: 3	Revision Date: 04-08-2025	Issued by: Dr. Jitender Aneja, Convenor
Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda		
Reference: National Ethical Guidelines for Biomedical and health research Involving Human Participants. Indian Council of Medical Research, 2017 and New Drugs & Clinical Trial Rules, 2019.		

- Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR): Any untoward medical occurrence that at any dose:
  - Results in death
  - Is life-threatening.
  - Require inpatient hospitalization or prolongation of existing hospitalization.
  - Results in persistent or significant disability/incapacity.
  - Is a congenital anomaly/birth defect.
- **Investigational Product:** A pharmaceutical or biopharma form of an active ingredient or placebo bein tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated/ packaged) in a way different from the approved form, or when used fo an unapproved indication, or when used to gain further information about an approved use.
- **Subject/Trial Subject:** An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.
- **Principal Investigator (PI):** If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- **Sponsor:** An individual, company, institution, or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.
- **Clinical Trial/study report:** A written description of a trial /study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects in which the clinical and statistical description, presentations and analysis are fully integrated into a single report.
- **Inspection:** The act by a regulatory authority/ies of conducting an official review of documents, facilitie records, and any other resources that are deemed by the authority/ies to be related to the clinical trial an that may be located at the site of the trial, at the sponsors and/or contract research organizations (CROs facilities, or at other establishments deemed appropriate by the regulatory authorities.

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

	STANDARD OPERATIVE PROCEDURES ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA	SOP No
	Procedures & Responsibilities:	
	❖ Chairman I. The Chairman of the IEC shall be presiding overall meetings of IEC. II. The Chairman will be responsible for affixing the date of meeting(s) of EC in consultation with member secretary of EC. III. The Chairman will be responsible to sign the letters/applications/notices/circulars on behalf of IEC to be sent to offices outside institution. However, in absence of Chairman, the Member Secretary may sign on the behalf of the Chairman, In absence of Chairman, other members outside institution among the members present for the IEC meetings, will be nominated as acting Chairman for that meeting. ♦ Member Secretary /Convener: I. Co-ordinates activity of writing, reviewing, distributing, and amending SOPs II. Maintains files of all previous SOPs and current SOP III. Receive, record, verify completeness and allot reference no. IV. Schedule meeting (physical/virtual), Prepare Agenda, invite members. V. Record agenda and Minutes of meeting. VI. Arrange meeting at an earlier date to evaluate SAE as per notification in consultation with the Chairman. VII. Circulate agenda/minutes of meeting/ other correspondence on the behalf of chairman for internal circulation among members/PI/Stakeholder in consultation with Chairman. ♦ IEC Members: All IEC members at the time of enrollment shall provide a copy of their CV as per the ICMR format. They shall be introduced and trained in appropriate Ethical Guidelines of the Indian Council of Medical Research (ICMR 2017) as well as other relevant guidelines such as New Drugs and Clinical Trial Rules, 2019 followed by discussion on all the contents of the SOP and shall be provided a copy of the current SOP. In case, SOP is revised, all the members shall be made aware of the changes and a copy of amended SOP shall be provided to them.	

- Principal Investigator: The application duly completed should be submitted to the office of IEC at least two weeks in advance of the scheduled IEC meeting. In addition to regulatory and other document submission, the PI will submit the following information.

1. Each subject in clinical trial to be enrolled only after obtaining audio and video consent as per DCGI guidelines.
2. Sponsor to provide free medical management in case of injury in clinical trial to the subject as per New Drugs and Clinical Trial Rules, 2019 (Reference: New Drugs and Clinical Trials Rules, 2018-Gazettee Notification-March 19, 2019, No. 200)
3. if required "as per the opinion of investigator", or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.
4. Undertaking from the PI for the vernacular translations of the concerned trial documents (Annexure VII)
5. Undertaking from the PI that the data acquisition for the current study/trial will not start prior to provision of IEC approval (Annexure VI)
6. A report of the clinical trial on a quarterly basis. (Annexure IV)
7. A report of the clinical trial six monthly. (Annexure V)
8. A report of each serious adverse event (requiring hospitalization, additional treatment, resulting in disability or death) about the study.
9. IEC to be mandatorily informed of the amendment/revisions to any study related document as well as patient safety related information.
10. In case of need for hospitalization of the subject in study/ trial, the PI shall report all serious adverse events (SAE) to the IEC and the licensing authority within 24 hours.
11. In case of any serious adverse event occurring in the clinical trial a narrative report after due analysis shall be forwarded by the PI to chairman of EC and the chairman of the expert committee constituted by licensing authority within 07 calendars days.
12. SAE reporting timeline for sponsor: 14 calendar days from "awareness of SAE/Death" and not "Occurrence/onset of SAE."
13. The sponsor or its representative and the investigator shall forward their reports on SAE of death after due analysis to DCGI, HOI, EC within fourteen days of the "knowledge of occurrence of SAE of death"
14. Study completion and discontinuation along with reasons.
15. To submit justification for approval to restart study discontinued earlier.

Procedure:

(I) Projects must be approved by the IRC (Institute Research Committee) for administrative assessment of justification, relevance, and benefits to institution, before presentation to Ethics Committee.

(II) All funds should be routed through finance and accounts Department, under separate head for each project.

(III) No direct/indirect individual financial benefit should be taken by any faculty member.

(IV) The project personnel/s, if involved should be duly approved by IRC. Appointment of medical person should be routed through MS and non- medical person through HRD.

(V) It should be ensured that the project work by the AIIMS Bathinda faculty/staff is not carried out at the expense of medical care of other patients or routine departmental work during duty hours.

(VI) At the end of the project, the report should be submitted on the prescribed format.

(VII) In case of Serious Adverse Event occurring in clinical trial after due analysis along with opinion on financial compensation will be forwarded to the licensing authority within 14 calendar days of the occurrence of the SAE.

Submission of Proposal by PI:

(I) Submission for RAC approval (Annexure II)

(II) All documents will be addressed to the Chairman, Institutional Ethics Committee.

(III) PI is required to submit the proposal by himself or nominee to the IEC with two hard copies of his/her application letter and two hard copies each of the following documents along with soft copies of these documents at least four weeks before the scheduled meeting in a prescribed format. (Annexure III)

(IV) Final protocol with all amendments, investigator's Brochure, safety mailing, Drug Controller General of India (DCGI) approval, Directorate General of Foreign Trade (DGFT) approval (where applicable), Complete insurance Policy (with schedule note showing the name of the PI and the name of the Institute along with insurance certificate of trial etc, and any other safety related information

(V) Informed consent form (inHindi, Punjabi, English), patient questionnaires, patient diaries and patient information sheet in English and its translations in local vernacular languages and their back translation with appropriate translation certificates.

(VI) Any other project-specific document (s).

(VII) After the approval, one copy of Serious Adverse Effects (SAE)/Council for International Organizations of Medical Sciences (CIOMS)/Appendix needs to be submitted.

(VIII) Self-certification of the vernacular translation for validity of content and Intent of various documents (Annexure VII).

(IX) Self-certification that the work will be started only after the approval and that no participant enrollment has been done before the ethical approval (Annexure VI)

(X) Registration with CTRI when required and an undertaking in this regard shall be submitted to the IEC before the start of the trial.

(XI) Expedited reviewed (In case any addition / deviation/ SAE). No expedited approval will be given without the above-mentioned documents.

(XII) Current resume/curriculum vitae of the Principal Investigator/Co Principal Investigators/ Co-Investigators/ Sub- investigator(s).

(XIII) All ADRs should be reported in a proper format as given below to give proper information on the first page of covering letter

Sr. No	Pt. ID	SAE No	Site (Country)	Event terminology	Type of report (initial/ follow up)	Study Drug relationship	Out come

(XIII) Any project personnel leaving or joining a particular protocol will be brought to the notice of IEC and status of trial to be decided by the IEC (within 24 hours).

(XIV) Information regarding the admission and discharge of all the trial subjects, in the event of an ADR,will be sent to IEC within 24 hours.

(XV) The Ethics committee is to be notified of any payments to be made to the study participants towards reimbursements of incidental expenses or otherwise.

(XVI) Clinical Trial Agreement (CTA).

a) All the Clinical Trial Agreements will be Tripartite and Principal Investigator as 2nd Party and "AIIMS Bathinda" as 3rd Party.

b) CTA (Draft) should be submitted before getting written approval of the trial.

c) The Tripartite CTA will be signed only after IEC approval.

d) Copy of CTA should be submitted to the office of IEC immediately.

(XVII) The INSTITUTIONAL ETHICS COMMITTEE is to be informed for any purposed retention items/gifts offered to the study participants. No retention items/gifts to be given to any study participant without the permission of INSTITUTIONAL ETHICS COMMITTEE.

Submission of Final Report of the Study : At the end of the study the PI shall submit final report (before Publishing the data) of the study to IEC (Annexure XI)

IEC Meeting: Time and frequency: The committee (Annexure I) will meet once in three months or as and when required. Advance notice 14 days before each meeting will be sent out to the IEC members, Principal Investigators along with the agenda. No protocol/documents shall be approved by circulation to the IEC members.

Quorum for the meeting : For review of each protocol the quorum of Institutional Ethics Committee should have at least 5 members with the following representations:

- Basic medical scientist (Preferably one Pharmacologist)
- Clinician
- Legal expert
- Social scientist/representative of non-governmental voluntary agency/philosopher/ethicist/theologian or a similar person.
- Lay-person from the community.

In addition to the medical experts the committee shall have:

- At least 1 member from a non-scientific field.
- At least 1 member from outside the institution
- At least 1 lady member

It is encouraged to invite non-member for formal opinion on specific indications in case-to-case basis. (Non-member experts will not be allowed to vote).

Procedure for the meeting:

(I) The meeting will be called to convey decisions on project submitted.
(II) Minutes of the last meeting will be approved.
(III) All the proposals (agenda wise) will be discussed in sequence.
(IV) The PI or study team member may be called to meeting to present the study or answer specific queries. However, he/she will not participate in the decision making/voting process of that study even if he/she is a regular member of the IEC.
(V) A study team member including the Principal Investigator will be deemed as an interested party about the review.
(VI) The Member Secretary designated by the Chairman, will record the minutes of the meeting, and circulate the same to the members within two weeks of the meeting.
(VII) The study team member's non-participation in the decision making/voting process will be recorded in the response letter from the IEC.
(VIII) The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend/reject/suggest modifications for a repeat review or advise appropriate steps. If subject experts are invited to offer their view, they will not take part in the voting process.

(IX) The committee will give its opinion on the project in one of the following ways (Annexure X)
- Approval
- Disapproval
- Needs Modification before approval
- Discontinuation of previously approved project.

(X) The IEC will issue its opinion (Approval, Disapproval, Needs Modification before approval, Discontinuation of previously approved project) to PI within 15 days of the meeting.

(XI) Any amendment to a study-related document will be discussed on the regular meeting of the committee. The decision will be minute recorded.

(XII) The Agendas/ Minutes/ Approvals/ Disapprovals/ letters/ Clarifications shall be signed by the Chairman/Member Secretary on behalf of IEC.

Note: The Institutional Ethics Committee working procedure compliance with ICH-GCP guidelines and trials are conducted as per guidelines of New Drugs and Clinical Trial Rules, 2019 and ICH- GCP.

Availability of the SOPs: A list of members, their qualification and affiliation is being maintained by the IEC. A copy of the IEC composting and operation procedures in to be made available to any member of the Hospital/Institute for filing of research projects, upon written request for the same to the IEC.

IEC Fees and Charge:

(I) The PI will also be responsible for submitting the fee for institutional overhead charges as well as fees for Ethical Committee in favor of "Institutional Ethics Committee Fund" The IEC will charge a fee as follows to cover the expenses and charges for the use of institutional infrastructure **(for the sponsored projects)**

- IEC Fees is Rs. 30,000/- (Exclude TDS / after all deductions) to be paid during the submission of the clinical trial.
- Institutional overhead charges as 10% of total budget (under special conditions, it can be modified on case-to-case basis)

(II) For the extension studies a fee of Rs. 30000/- will be charged and this extension study will be treated as separate study for the purpose of Ethical consideration.

(III) However, those projects involving human subjects which are funded by government/government aided/not for profit research agencies/organization or are PI initiated studies, submitted by faculty members/students will be exempted for this IEC fees of Rs. 30,000/- and institutional overhead charges. These Projects will be considered only after approval from RAC.

Financial Transactions:

(I) The amount of fee for clinical trial should be received in the name of institution "Institutional Ethics Committee Fund, AIIMS, Bathinda" and not in the name of PI. The cheque/DD received should be deposited with finance and accounts departments of the institution by the PI and the proof of the same to be submitted to IEC office.

(II) The PI should inform the Finance and Accounts Department with a copy of the agreement so that non-tax deduction Certificate is obtained from the Income Tax Department of non-deduction of TDS by the organization giving the payment to the institution.

(III) The Finance and Accounts Department will send the said certification to the PI for onward submission to the sponsor organization enabling the company not to deduct TDS on the amount paid to institution from time to time during the year for which the certification is issued.

(IV) The institution will open project wise separate accounts in the accounts books/subsidiary books of the institution.

(V) The PI will advise the Finance and Accounts Departments to make payments, with necessary supporting documents from time to time.

(VI) The Finance and Accounts Department will make the payment by way of Cheque/DD/Online mode as per advice of PI from time to time.

(VII) The Finance and Accounts Department will keep an account of all the transactions, make necessary TDS deductions deposit TDS so deduced, issue TDS certificates, file TDS returns etc and submit an account to the PI as and when required. The accounts of Institutional Ethics Committee will be audited every financial year by the Accounts Department of AIIMS, Bathinda.

(VIII) The PI can take imprest money out of the funds received to meet the petty cash expenses and will submit a monthly detail of such expenses to Finance and Accounts Department.

(IX) The PI will maintain all the records/documents with himself to the satisfaction of the sponsor organization.

(X) The PI should be managing the account and amount to be withdrawn will be signed by Principal Investigator and Medical Superintendent.

(XI) The distribution of amount should be as per CTA and PI should be responsible for the salaries of their concerned staff and other cost related to the trail. Institute shall not be responsible for any trial related expenditure. Charges to the patient' as mentioned in CTA will be paid by the PI through the funds earmarked for the same.

(XII) The PI will inform the Finance and Accounts Department. For the admission or investigation of subjects enrolled in trial for onward adjustment of funds for the same. No subject enrolled in the study pay for any services after giving informed consent for the participation in the trial.

....

Record:

All study related correspondence will identify the study documents by Version Number/Date and Title. Correspondence between the IEC and the PI/Study team and other relevant records (all the related documents regarding the protocol, minutes of meeting, composition etc.) will be retained for a minimum period of five years after completion of trial.

Audit and Inspection:

Internal Audit: The IEC can nominate an Inspection Team (at least 2 members) to inspect the documents pertaining to trial with prior intimation to principal Investigator (PI).

External Audit: The credentials of the officials shall be verified and letter for audit will be received. All the documents required by the auditors shall be provided to them under receipt.

Annexure-I

IEC Meeting

The Committee will meet on dated_____at_____

Total No. of Protocols_____

List of protocols to be discussed:

Sr. No.	Title of Study Protocol	Name of Principal Investigator	Name of Primary Reviewer	Name of Secondary Reviewer

All members are requested to attend the meeting in time.

Member Secretary

Annexure-II
Submission of Proposal for RAC Approval

DETAILS OF THE RESEARCH PROJECT

1. Title of the project
2. Objectives
3. Summary of the proposed research (up to 500-750 words) indicating overall aims of the research and importance of the research proposal and justification. Application of the work in the context of national priorities of medical research, if any, may also be mentioned.
4. Present knowledge and relevant bibliography including full titles of articles relating to the project.
5. Preliminary work already done by the Investigator on this problem.
6. Detailed research plan.
7. Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.
8. Bio-data and List of important publications of last 5 years of the all the investigators in the relevant fields (enclose reprints, if available)
9. Budget requirements (with detailed break-up and full justification) including Institutional fee and IEC fee.

Principal Investigator

Annexure-III

Check list of required documents to be submitted: (Two Copies each) (Please Tick)

- RAC approval
- EC fees receipt (as per SOP)
- Undertaking by PI
- Curriculum Vitae of Principal Investigator/Co-investigators
- Investigator's Brochure (IB)
- Study protocol
- ICF in languages (English, Hindi, Punjabi)
- DCGI approval
- Import/Export license (where applicable)
- Serious Adverse Events at any other site where study is going on
- CTA (Clinical Trial Agreement) Draft for Approval
- Budget of the trial
- Complete Insurance Policy of the trial along with Insurance Certificate and schedule Showing the name of the Hospital/Principal Investigator's
- Name of project staff/personnel along with photocopies of their I-Card.
- CTRI no. (wherever Applicable)
- Self-Certificate for Current study Status
- Self-Certificate for Vernacular Translation
- Self-Declaration to submit complete report on study completion

Annexure-IV

Quarterly Study Status Report

Date of IEC approval
Study start date
Report for the period of of_____,20_____
Quarter No. .... Of .....
Number of the Protocol_____
Title:_"

PI Name in Study_____Department_____

Co-PI Name in Study_____Department_____
Co-PI Name in Study_____Department_____
Co-PI Name in Study_____Department_____

IEC Approval Letter No._____Dated_____

Heading	Number
Patients Screened	
Patients Enrolled	
Patients who completed the study/protocol	
Patients taken out form the study	
Patients who withdrew consent	
Patients lost to follow up	
Patients Died	
Patients of protocol Deviations/Violations	
SAE at study site	

Sign of PI with Stamp

Annexure-V

Annual Study Status Report

IEC approval letter No._____Date_____

- Proposed number of patients to be enrolled from this site.
- Number of patients screened till date.
- Number of patients who failed screening.
- Number of patients enrolled in the study till date.
- Number of patients who have completed the study.
- Number of patients who expired during study period.
- Number of patients who withdrew consent.
- Number of patients who were lost to follow up.
- Number of patients enrolled in this study all present.
- Date on which first patient was enrolled.
- Due date of last patient enrollment:
- Number of SAEs (at own site):
- Due date for end a study:
- Due date for last study related Procedure:

Date:

Sign of PI:

Annexure-VI

Undertaking by PI to initiate study/trial after IEC Approval

I Dr._____Presently employed in_____as_____and Principal Investigator for the protocol entitled "_____" here by certify that above mentioned study has not been started yet and it will be started only after approval of IEC (Institutional Ethics Committee)

Regards,

Sign of PI with designation (with date and stamp)

Annexure-VII

Self -Certificate of the Vernacular Translation

I Dr._____Presently employed in_____as_____and Principal Investigator for the protocol entitled "_____" here by certify that I am personally satisfied and have verified the translation and the back translation of the following documents:

Sr. No	Documents	Version/Date

Regards,

Sign of PI with designation (with date and stamp)

Annexure-VIII

Undertaking by IEC Member

I._____S/o D/o_____presently working as IEC member at _____hereby confirm that I have been introduced about the regulation regarding functioning of IEC and requirements expected of IEC member. I have been told about the current/SOP in place and received a copy of the same.

With regards,

Member's Name:

Designation:

Annexure-IX

Performa for Receipt of Updated SOP by IEC Member

I._____S/o D/o_____presently working as IEC member at _____hereby confirm that I have been provided with Amended SOP and fully understood the same.

With regards,

Member's Name:

Designation:

Annexure X
IEC Assessment Report on Study Protocol

Protocol Number:

Protocol Title

Number of review	1st Review	2nd Review	3rd Review
Principal Investigator:			Department:
Date of Initial Review by IEC:		Date of Last Review:	
The IEC Decision recorded in the meeting minutes: (meeting held on)			

Opinion of the reviewer:

Revision or Modification according to the recommendation	Yes	No: Explain:
Approved	Yes	No
If disapproved, reasons for disapproval		
Further revision or modification required		
To be discussed at the forthcoming full board meeting		
Any Other		

Name of the Reviewer: 1)

Signature:

Date:

Name of the Reviewer: 2)

Signature:

Date:

Final Decision: Approved **Yes/ No**

Signature of the Member Secretary/ Chairperson:

Date:

Annexure XI

Submission of Final Report

1. Title of the Project:
2. Principal Investigator and Co-Investigators
3. Implementing Institution and other collaborating Institutions
4. Date of commencement
5. Duration
6. Date of completion
7. Objectives as approved
8. Deviation made from original objectives if any, while implementing the project and reasons thereof.
9. Experimental work giving full details of experimental set up, methods adopted, data collected supported by necessary tables, charts, diagrams, and photographs.
10. Detailed analysis of results indicating contributions made towards increasing the state of knowledge in the subject.
11. Conclusions summarizing the achievements and indication of scope for future work.

(Principal Investigator) (Co-Investigator)

Annexure XII
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BATHINDA
INFORMED CONSENT FORM

Study Title_____
Study Number
Subject's Full Name
Date of Birth/Age
Address

1. I confirm that I have read and understood the information sheet dated___for the above study and have had the opportunity to ask questions.

OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions

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

3. I understand that the sponsor of the clinical trial/project, 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. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. 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 purpose(s) and does not reveal my identify or personal information without my permission.

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:
Signatory's Name_____ Date
Signature of the Investigator_____ Date
Study Investigator's Name _____
Signature of the Witness_____ Date

Name of the Witness _____

ANNEXURE - XIII

Format for Participant Information Sheet

Study Title:

Principal Investigator's name:
Principal Investigator's title:
Principal Investigator's Telephone number:
Co-Investigator's Name:

You (For Children: Your Child; For unconscious participants and /or those unable to give consent (including fetuses): Your.....(state relationship is)....) is/are being invited to take part in a research study, before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – do not feel rushed or under pressure to make a quick decision.

- **Why is this study being done?**
- **Who is organizing and funding this study?**
- **Why am I being asked to take part?**
- **How will the study be carried out?**
- **What will happen to me if I agree to take part?**
- **What are the risks?**
- **Will it cost me anything to take part?**
- **Is the study confidential?**

Signature of Principal Investigator

Josephlmathew