**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



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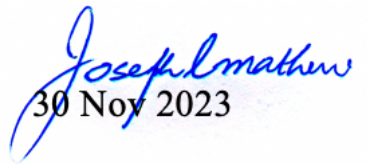

of the institution.

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 |
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| 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<br>• Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations<br>• Ratify minutes of the previous meetings<br>• 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.<br>• Seek COI declaration from members and ensure quorum and fair decision making.<br>• Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc |





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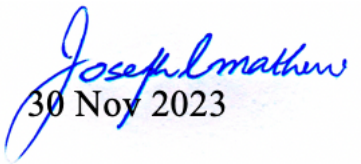
| 2. | **Member Secretary/ Alternate Member Secretary** (optional)<br>Affiliated Qualifications –<br>• Should be a staff member of the institution<br>• Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills<br>• Should be able to devote adequate time to this activity which should be protected by the institution | • Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review<br>• Schedule EC meetings, prepare the agenda and minutes<br>• Organize EC documentation, communication and archiving<br>• Ensure training of EC secretariat and EC members<br>• Ensure SOPs are updated as and when required<br>• Ensure adherence of EC functioning to the SOPs<br>• Prepare for and respond to audits and inspections<br>• Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.<br>• Assess the need for expedited review/ exemption from review or full review.<br>• Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.<br>• Ensure quorum during the meeting and record discussions and decisions. |







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| 3. | **Basic Medical Scientist(s)**<br>Affiliated/ non-affiliated Qualifications –<br>• Non-medical or medical person with qualifications in basic medical sciences<br>• 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<br>• For clinical trials, pharmacologist to review the drug safety and pharmacodynamics. |
| 4. | **Clinician(s)**<br>Affiliated/ non-affiliated Qualifications –<br>• 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<br>• Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)<br>• Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.<br>• Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents. |





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| 5. | **Legal expert/s**<br>Affiliated/ non-affiliated Qualifications -<br>• Should have a basic degree in Law from a recognized university, with experience<br>• 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.<br>• Interpret and inform EC members about new regulations if any |
| 6. | **Social scientist/ philosopher/ ethicist/theologian**<br>Affiliated/ non-affiliated Qualifications –<br>• 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.<br>• Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any<br>• Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns. |
| 7. | **Lay person(s)**<br>**Non-affiliated Qualifications –**<br>• Literate person from the public or community | • Ethical review of the proposal, ICD along with translation(s). |

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| | • Has not pursued a medical science/ health related career in the last 5 years<br>• May be a representative of the community from which the participants are to be drawn<br>• Is aware of the local language, cultural and moral values of the community<br>• Desirable: involved in social and community welfare activities | • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.<br>• Serve as a patient/participant/ community representative and bring in ethical and societal concerns.<br>• 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.

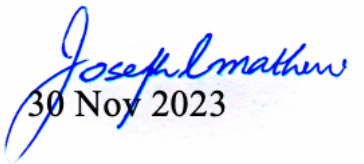
c. Any change in the relevant guidelines or regulatory requirements will be brought to the attention of all EC members.
d. The IEC members shall be aware of local, social and cultural norms and emerging ethical issues.

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.



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- 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** |
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| 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 |

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| | 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.<br>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



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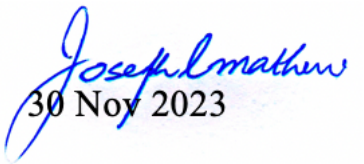

ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.

- 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.



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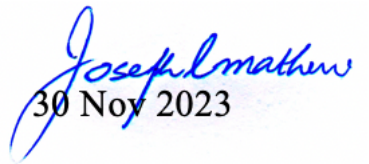

n. The primary and secondary reviewers will brief the members about the study proposal and review carried out as per IEC SOPs.

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).**





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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.





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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**



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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



| IEC, AIIMS, Bathinda | | |
|---|---|---|
| Document No. 1 | Document Type: SOP | Version: 1 |
| Prepared by: Dr. Jitender Aneja | Section: General Terms & References | |
| Revision No: 0 | Revision Date: | Issued by: Dr. Jitender Aneja, Convenor |
| Approved by: Dr. Joseph Mathew, Chairman, IEC, AIIMS, Bathinda | | |

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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.



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|---|---|---|
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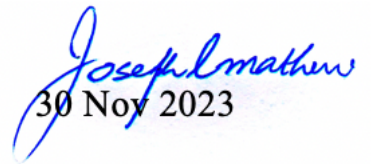

**Annexures:**

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.



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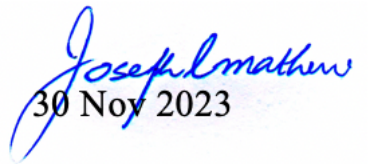

IEC/AIIMS/BTI/SOP/TOR/Annex 1:

**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) |



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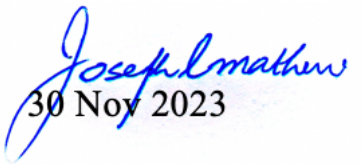
| 24. | Any additional document(s), as required by EC (such as other EC clearances for multicentric studies) |
| 25. | Protocol |







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 |





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IEC/AIIMS/BTI/SOP/TOR/Annex 3:

**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.<br>• 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.<br>• 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.<br>• 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.<br>• The IEC shall review plans for risk management, including withdrawal criteria with rescue medication or procedures. |





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| | | • The IEC shall give advice regarding minimization of risk/ discomfort wherever applicable.<br>• 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.<br>• Participants shall be able to opt out at any time without their routine care being affected.<br>• No individual or group of persons must bear the burden of participation in research without accruing any direct or indirect benefits.<br>• 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.<br>• 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.<br>• 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.<br>• The proposed research shall not lead to any stigma or discrimination. Harm, if any, should be minimized.<br>• Plans for communication of results to the community at the end of the study should be carefully reviewed.<br>• 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.<br>• 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.<br>• 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:<br>• the process used for obtaining informed consent, including the identification of those responsible for obtaining consent and the procedures adopted for vulnerable populations;<br>• the adequacy, completeness and understandability of the information to be given to the research participants, and when appropriate, their LARs |