	Guidelines for Institutional Ethics Committee (Humans)/IEC		Document No	IITRPR/IEC/001
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1. Preamble

This document aims at supporting the efficient operation of Institutional Ethics Committee (Humans) / IEC at the Indian Institute of Technology Ropar, Rupnagar-140 001, Punjab (IIT ROPAR), and to establish a fair and consistent assessment process for proposals submitted to it for review. The IEC will consider protocols involving research on human subjects, biological samples from human subjects, and data from human subjects.

2. Role of the Institutional Ethics Committee

As stated by the Indian Council of Medical Research (ICMR), the role of IEC will be as follows: "all proposals for biomedical and health-related research will be subject to IEC approval as a part of the IEC's mandate. Proposals involving biological samples, vulnerable populations, and/or sharing of private information involving human subjects are also included in order to protect the rights, safety, and general welfare of all actual and potential participants in research that will be carried out by IIT ROPAR researchers. No matter how essential the research's objectives are, the health and wellbeing of subjects must always come first".

The IEC will make sure that the proposed approach/protocol complies with the four fundamental principles of research ethics: autonomy, beneficence, non-malfeasance, and justice.

The informed consent process, risk-benefit ratio, burden and benefit allocation, and provisions for suitable compensations will all be examined by the IEC, as per the need.

IEC will review proposals/protocols before the initiation of the study, and after the completion of the study through documented procedures. IEC will not assess or approve a study retrospectively.

3. Purpose of IEC

The purpose of IEC at IIT Ropar is to ensure the quality and technical excellence, and ethical review of research proposals and ongoing studies in accordance with the ICMR guidelines, 2017. The IEC will assess the study's scientific rationale, scope, and methodology, as well as its ethical

aspects. The committee will consider the potential risks to participants and justify them as well as expected benefits to participants/community. The documentation required to ensure privacy will also be reviewed.

4. Scope of IEC

The scope of IEC is to design SOPs, which covers the procedures for reviewing, writing, amending, and distributing SOPs. Relevant comments made during a study's discussion and deliberation will be recorded in minutes of meeting (MoMs). The IEC's decision will be communicated to the principal investigator.

5. Composition of IEC

a) IEC will have a multidisciplinary composition, as per the norms laid down by the ICMR. The number of persons in the IEC will be determined by the requirements and nature of the task.
b) The total number of members in an EC will be ideally between seven and 15 and at least five members will be present to meet the quorum requirements.
c) The EC will have both medical and non-medical members/technical and non-technical members.
d) Ideally, 50% of the members will be from outside the institution.
e) ECs will be multi-sectoral and multi-disciplinary.

The composition of IEC at IIT ROPAR will be as follows:

i. **Chairperson**- the Chairperson of IEC will be from outside IIT ROPAR, with experience serving in an EC. He will be responsible for conducting EC meetings and their independent and efficient functioning. He will make sure that all members (particularly non-technical and non-affiliated) actively engage in all discussions. He

will nominate a committee member as an acting chairperson in case of his and/or the vice-chairperson's absence at a meeting. He will seek a conflict of interest and assure fair decision-making. He will also address issues involving complaints against researchers and EC members and requests for the use of EC data.

ii. **Legal expert**- the legal expert will be from outside IIT Ropar with a degree in law from a recognized university with experience. He will be responsible for conducting an ethical review of the proposal, clinical trial agreement, MoU, informed consent documents (ICD), and its translations, researcher's undertaking, and protocols specific permissions. He should also interpret and notify EC members of any new regulations.

iii. **One or more scientists**- one or more biomedical scientists will come from the departments/centers of IIT Ropar. They will ensure the ethical and scientific review with particular attention on research design, benefit-risk investigation, methodology, intervention, protocol deviation, serious adverse events (SAE), protocol deviation, keeping up the review procedures, and progress and completion reports.

iv. **One or more Clinicians**- one or more clinicians will come from hospitals/medical colleges/medical university/medical institutes outside IIT ROPAR. He will ensure the scientific and ongoing review of the protocol, including benefit-risk investigation, methodology, site of study, protocol deviation, statistics, and progress and completion reports. He will also inspect medical facilities, management, and compensation.

v. **One or more philosophers/social scientists/theologians/ethicists**- will come from the Humanities and Social Sciences department of IIT ROPAR and, if not available, will come from other institutes/universities. He will conduct an ethical review of the proposal and ICD and its translations. He will serve as a participant representative and bring up societal and ethical issues.

vi. **Lay person**- lay person will have no background in biomedical research. The lay person will also be a member of the local community. Lay person will be not be affiliated to IIT Ropar. He will conduct an ethical review of the proposal, ICD, and its translations. He will serve as a participant representative and bring up societal and ethical issues.

vii. **Member Secretary**- the member secretary will come from IIT ROPAR. He will be responsible for a well-organized review of proposal. He is also responsible for scheduling EC meetings and its documentation. He will also make sure that SOPs are updated and respond to

audits and inspections.

The Member Secretary or Chairperson may invite subject matter experts, if needed, to hear their opinions.

6. Conditions of EC member's appointment

All EC members, including the chairperson, will be appointed by the head of the institution, the Director.

Guidelines for EC members

i. Name, gender, profession, and affiliation of IEC members will be publicized.
ii. They will be required to undergo training to update their knowledge and skills.
iii. They will provide a recent CV and required training certificates.
iv. They will follow the conflict of interest (COI) policy of EC and declare it at an appropriate time.
v. They will sign a confidentiality and conflict of interest agreement/s.
vi. They will be committed to understanding the need of research and providing protection to research participants.

Training for EC members

EC members should have initial and continued research education related to science and ethics of biomedical research.

i. All IEC members will be exposed to ICMR Guidelines for Research involving Human Subjects 2006, ICH-GCP guidelines and Schedule Y of Drugs and Cosmetics Act.
ii. IEC members will also receive introductory training in IEC SOPs and research bioethics and will be made familiar with ongoing opportunities for increasing their efficiency for ethical review.

iii. A new member will be called about 1 month before his/her appointment and will be requested to observe during the first board meeting. An introductory training will be given by the Member Secretary.
iv. The IEC members will be also be said to get ongoing training by attending workshops at least once every year.
v. The IEC will conduct workshops from time to time to train IEC members and institutional faculty members.
vi. Members will be trained in EC functions and SOPs, human research protection, and relevant regulations of the country.
vii. EC members will have to undergo training in human research protection, applicable EC SOPs and regulatory requirements related to them. All trainings must be documented.
viii. Any change in the relevant guidelines or regulatory requirements will be communicated to all EC members.
ix. EC members should be aware of social, cultural and local norms including emerging ethical issues
x. The institute will make arrangements to ensure that members receive the initial training in EC functions, SOPs and relevant regulations of the country (new drugs and clinical trial rules, 2019), ICMR national ethical guidelines, and GCP. The institute will also ensure that the certificates of the IEC members remain valid during their term as an IEC member.

7. Authority under which IEC is constituted

The Director of IIT ROPAR will constitute IEC. The IEC will be serviced by the office of the Dean of Research and Development (R and D) with delegated authority from the Director.

8. Requirements for membership

i. The term of the members is three years and renewable at the completion of the term.
ii. If a member is unavailable for long-term, a replacement can be found. A committee

member may submit his/her resignation from the committee stating the reasons to do so.

iii. Any change in the constitution of committee must be approved by the director.

iv. Each member is required to maintain absolute confidentiality regarding the deliberations of the committee.

v. All members must disclose conflict of interest, if any.

9. Quorum requirements and mode of meeting

The presence of at least five members will be required to meet quorum requirements and, at least, one representative from each of the following fields must be present to examine a proposal.

- Legal expert
- Clinician
- Social Scientist
- Basic Scientist
- Lay person

A minimum of one meeting will be held to consider each proposal/protocol that IEC receives for review, and no decisions will be made without proposal/protocol being discussed in a meeting. Proposal reviewed in expedited mode ("Expedited Review") may not be discussed in full board meetings. However, the committee will be kept informed of such a proposal and its status.

The committee meetings will be conducted in offline, online, or hybrid mode depending on the requirements.

10. Offices

Each IEC meeting will be led by the Chairperson, and if he or she is unable to attend the meeting, he or she will propose a co-chair for the meeting.

The Member Secretary will be in charge of setting up meetings, keeping track of agenda, and communicating with everyone concerned. The minutes of meeting (MoMs) will be written by the member secretary, and he will also send the comments to PIs after the meeting.

11. Application Procedures

i. IIT ROPAR faculty will be given an advance notice by email about the dates for proposal submission and IEC meetings.
ii. Submission guidelines will be available on the IEC page, linked to Research and Development webpage (https://www.iitrpr.ac.in/RnD/). The guidelines and formats may be amended by the Member Secretary, if required.
iii. The Principal Investigator (PI) will be required to turn in proposals in specified format and by the specified deadlines.
iv. Each proposal will have a number assigned to it in the following format: IITRPR-IEC/YYYY/Proposal No., where YYYY is the calendar year in which the proposal is submitted for review. The proposal No. will be assigned in the sequence it is received for IEC's review.
v. The proposal will be emailed to the Member Secretary as a single PDF file, signed by the principal investigator (PI), and containing all relevant information, including attachments like the informed consent documents (ICDs) and their translations.
vi. The Member Secretary will forward the proposals to IEC members by email for assessment and feedback.
vii. Members will express their opinions on the proposal and may ask for clarifications, as needed.
viii. Comments by members will be compiled by the Member Secretary and forwarded to the PI in advance so that PIs are ready to respond to requests for clarification.
ix. The PI is responsible for preparing the presentation for the IEC meeting, and only co-PIs may attend.
x. The proposal will be presented by each PI, followed by discussions
xi. IEC members will discuss the proposal, recommendation, and/or decision behind closed doors.
xii. The Member Secretary will email the PI with the recommendations and decisions

of the IEC regarding the proposal.

xiii. If revisions are required, the Member Secretary will communicate the same to PI, who will then carry out the revisions and prepare responses to comments. The PI will return the corrected proposal to the Member Secretary. The members will receive the updated version through email and they will then take a final decision.

12. Documentation (as per ICMR guidelines)

All research proposals/protocols will be submitted with following details:

i. The applicant's full name and designation- only IIT ROPAR employees, who are permitted to be PIs as per the institute norms, can apply.

ii. Information on the location of the site, institute, hospital, or field, where the research will be done.

iii. A detailed protocol of the proposal that includes the information on following:
   a. the scientific justification, including the outcomes of prior animal and human studies.
   b. the hypothesis.
   c. the study designs.
   d. the risks associated with the design of the study.
   e. the statistical basis for the structure of investigation.
   f. Any potentially harmful effects that can be adequately detected, avoided, or treated.

iv. The principal investigator (PI) will classify study-related risks as one of the following:

i. Less than minimal risk
Research for which there is no known harm to one's health, wellbeing, or finances.

ii. **Minimal risk**
The likelihood and potential severity of the harm or discomfort expected in the research are, taken alone, not larger than those typically encountered in daily life or when undergoing standard physical or psychological evaluations or tests.

iii. **Greater than minimal risk**

Research procedures that may include danger above and beyond what subjects are typically exposed to under normal physical or psychological evaluations or tests. Examples include experimental drugs, maximal exercise testing, biologics or medical devices, stressful psychological testing, or use of special populations.

v. The ethical concerns in the proposal and measures to address them.
vi. Enclosures, such as the Informed Consent Document (ICD) and its translations in other languages, as required, questionnaires, etc.
vii. All significant pre-clinical animal data and clinical trial data from other centers within the country or from abroad, if available for any drug or device trial.
viii. CVs for every researcher along with their recent publications during the last five years.
ix. Any need of regulatory clearances.
x. The project's funding source and necessary funds.
xi. Additional monetary concerns, particularly insurance-related ones.
xii. A commitment to inform IEC of Serious Adverse Events (SAE).
xiii. Statement of potential conflicts of interest.
xiv. Agreement to adhere to the relevant international and national regulations.
xv. A statement outlining following:
    a. payment to research participants as compensation for their time (including reimbursement for travel costs and access to healthcare).
    b. a description of indemnity plans, if any (in the event of injuries related to the study)
    c. a statement of the insurance coverage arrangements for research participants, if any, and all major prior choices (such as those resulting in an adverse determination or a changed protocol) by ECs or the planned study's regulatory bodies (whether in the same place or elsewhere) and a description of any changes made to the created on that account via protocol. The justifications for negative decisions should be provided.
xvi. Plans for publishing findings, whether positive or negative, while protecting the participants privacy and confidentiality.

xvii. Additional data relevant to the study.
xviii. Proposals will not be taken up for review by IEC, until all the information is provided

13. SOP for Terms of reference of the committee

The IEC will be constituted for a term of three years. The office of IEC, IIT Ropar will maintain the terms of reference, which includes

i. Requirements for membership.
ii. Terms of appointment as per the tenure of term.
iii. Removal, replacement, and resignation policy.
iv. Frequency of meetings.
v. Payment of the processing fee to the IEC for review and consultancy to members or invited experts (no fee).

The SOPs will be updated on a regular basis to reflect changing requirements. The terms of appointment of members can be extended for another term and a predefined percentage of members could be rotated on a regular basis. Preferably, the IEC will appoint people who have received bioethics training or are familiar with the country's ethical guidelines and laws.

14. SOP for vulnerable population

Individuals are considered vulnerable if they are economically and socially deprived, and are not capable of making a voluntary decision, or their autonomy is compromised and, hence, more prone to being exploited.

i. People in vulnerable populations will have an equal right to participate in research.
ii. Involvement of legally acceptable representative (LAR) is necessary in case the participant is unable to provide consent.
iii. The privacy of participants will be ensured.

iv. A special emphasis will be given to the protection of vulnerable populations to safeguard their safety, well-being, rights, and dignity.
v. If vulnerable group is only involved then the research will answer the health needs of the group.
vi. Only the full committee will accord approval and perform initial and continuing review of proposals involving vulnerable populations.

15. SOP for handling and mitigation of conflict-of-interest (COI)

COI can affect the research questions, recruitment of participants, publications, and ethical review of research. Following steps will be taken for identifying, managing, and mitigation of COI.

i. Development of procedures and policies to address COI and training of personnel on how to use them.
ii. Ensuring the accuracy and objectivity of the study by keeping an eye on it or examining the results.
iii. Researchers will make sure to disclose any COI (financial or non-financial).
iv. Researchers will make sure that they do not examine grants and papers filed by close colleagues, family, and/or students to avoid intellectual and interpersonal disputes.
v. IEC will assess each study in light of disclosed COI and make sure that appropriate mitigation measures are taken.
vi. IEC will also propose suitable management recommendations if COI is found at the institutional or researcher level.
vii. COI within the EC will be declared and managed in accordance with standard operating procedures (SOPs) of that EC
viii. If an IEC member has some COI, she/he will inform that to the member secretary/ chairperson and will not participate in the discussion/decision making during the time when that particular research project is discussed in the meeting. The member will neither participate in the discussion nor vote on that project. This will be noted in minutes.

ix. In case of conflict, the decision of the local EC based on relevant facts/guidelines/law of the land shall prevail.

16. Review procedures (as per ICMR guidelines)

i. The IEC meeting will take place on the dates set forth in the calendar of IEC meeting dates, and the schedule will be provided to PIs in advance through email.
ii. Proposals will be submitted by the deadline and will be considered for review in the order they have been received. The protocols submitted after the deadline will be considered in the next meeting.
iii. Prior to the meeting, one to two committee members (principal reviewers) will read the proposal and provide their feedback. The PI will receive these remarks in addition to a list of clarifications before the meeting. PIs will be required to be present at the IEC meeting when their proposal is being considered.
iv. After thorough consideration and discussion, decisions will be made (only members present).
v. PIs will be asked for explanations/revisions, if necessary.
vi. If required, outside consultants and experts will be contacted to provide their insight on certain aspects of the proposal.
vii. Decisions will be recorded in minutes of meeting (MoMs), confirmed electronically by the Chairperson and members, and ratified at the following meeting.
viii. Any deviation in the review procedure must have the approval of the Chairperson.

17. Elements of review

i. The scientific rationale, hypothesis, design, and execution of the study.
ii. If required, approval from competent scientific review committees.
iii. Analysis of expected risks and damages.
iv. A review of potential advantages.
v. The process of choosing subjects, including the inclusion/exclusion criteria, the withdrawal criteria, and other factors, like the details of the advertisement.
vi. When required, the management of accidents, bad events, etc. related to research.

vii. Provisions for compensation.
viii. ICD and its translation in other languages, as required, and participant information sheet
ix. Privacy and confidentiality protection.
x. Plans for reporting and data analysis.
xi. Compliance with legal requirements and regulations
xii. Competence of PIs.
xiii. Infrastructure and facilities at study sites, where appropriate.
xiv. Requirements for patient withdrawal, study suspension, or study termination.

18. Expedited review

An expedited review may be conducted without a full board meeting in following situations:

i. Such proposals will be considered by few members (1-2 members, with permission from the Chairperson) only if the proposals involve minimal risks or less than minimal risks. The PI will provide a basis for an expedited review. The primary reviewer(s) depending on the contents of the proposal, may decide to review and approve it in an expedited mode or assign it for the review by full board.
ii. For proposals that have been approved in principle but subject to minor changes, following procedure will be followed:
    a. The Member Secretary will send email to PIs regarding the IEC's recommendations.
    b. The Member Secretary will receive the revised document electronically from PIs.
    c. The updated document will be sent to the members by email.
iii. Members will give their feedback on the updated document and, if necessary, their consent for the approval of the proposal will be collected by email.
iv. Expedited review will not be allowed for proposals that are required to be resubmitted to the committee for a subsequent meeting.

19. Making decisions (as per ICMR guidelines)

The following decision-making procedure shall be used:

i. Before reaching a conclusion by consensus, the IEC members will discuss numerous

issues.

ii. Members who might have conflicts of interest will abstain from voting. Prior to the application assessment and recording of minutes of meeting (MoMs), the Chairperson must be informed of any such conflicts of interest.

iii. Decisions will be made only at meetings with a full quorum.

iv. The decision will be made by members only, and the experts/consultants will only provide their insights and cannot take part in taking a decision.

v. A proposal/protocol may be approved, revised, or rejected. Reasons for rejection and revisions recommended will be provided.

vi. In cases of conditional decisions, clear suggestions for revision will be provided.

vii. The process for getting the proposal re-evaluated either as expedited review or re-submission to a subsequent meeting will be outlined. After receiving IEC recommendations, the request for re-review will be presented within 180 days.

viii. Any appeal of the IEC's decision must be submitted first to the IEC Chairperson, who has the authority to revaluate, affirm, or reject the recommendations while taking the PI's input into account.

ix. If a request is turned down by the IEC, an appeal may be made to the Director of IIT ROPAR. The Director may determine himself/herself or appoint a committee to decide on the request, after seeking clarifications from the Member Secretary. In such circumstances, the decision by the Director will be final.

x. The IEC at IIT ROPAR will grant approval for research projects. For IEC approval of regulatory studies, PIs should contact ethical committees that are registered with the DCGI. In the latter scenario, an official letter of IEC permission will be sent to IEC at IIT ROPAR.

20. Communicating the decision

i. The Member Secretary will email PIs recommendations for revision and re-review as well as any other decision.

ii. The PI will be provided with reasons for rejection.

iii. The Member Secretary will prepare the acceptance letter based on the members'

agreement to approve a proposal, either during the IEC meeting or after reviewing a revised document received after the IEC meeting.

iv. The Member Secretary will sign the approval letter on behalf of the IEC Chairperson.

v. The PI will receive both the original approval letter and a soft copy of it.

21. Follow up procedures

i. The PI must monitor the study.

ii. All SAEs and the interventions undertaken should be intimated.

iii. Protocol deviations, if any, must be disclosed to the IEC prior to the divergence and must be properly justified. The protocol must then be presented again for new approval.

iv. The study's new information should be communicated.

v. A summary of the data collected so far and reasons for study's premature discontinuation should be provided.

vi. Changes in investigators or study locations must be reported.

vii. At the conclusion of the study, a final report is required.

22. Archiving and record-keeping

i. The curriculum vitae (CV) of every IEC member.

ii. Copies of all study protocols, progress reports, and SAEs with attached documents.

iii. Minutes of all meetings (Moms).

iv. A copy of the current, relevant national and international regulations and ethical standards for research.

v. Copy of all correspondence with members, researchers and other regulatory bodies.

vi. Final report on the projects that were approved.

vii. The soft copy documents will be archived at IEC for a period of five years after the study is approved.

23. Updating IEC members

The IEC members will be regularly updated about new guidelines, and they will be encouraged to take part in national and international training programs in research ethics to uphold the standard of the review process and stay aware with the latest developments in the area.

24. Reference

Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research, Indian Council of Medical Research.

25. Nomenclature

CV: Curriculum Vitae
ICD: Informed Consent Document
ICMR: Indian Council of Medical Research
IEC: Institutional Ethics Committee (Humans)
MoM: Minutes of Meeting
PI: Principal Investigator
R&D: Research and Development
SAE: Serious Adverse Events
SOP: Standard Operating Procedures