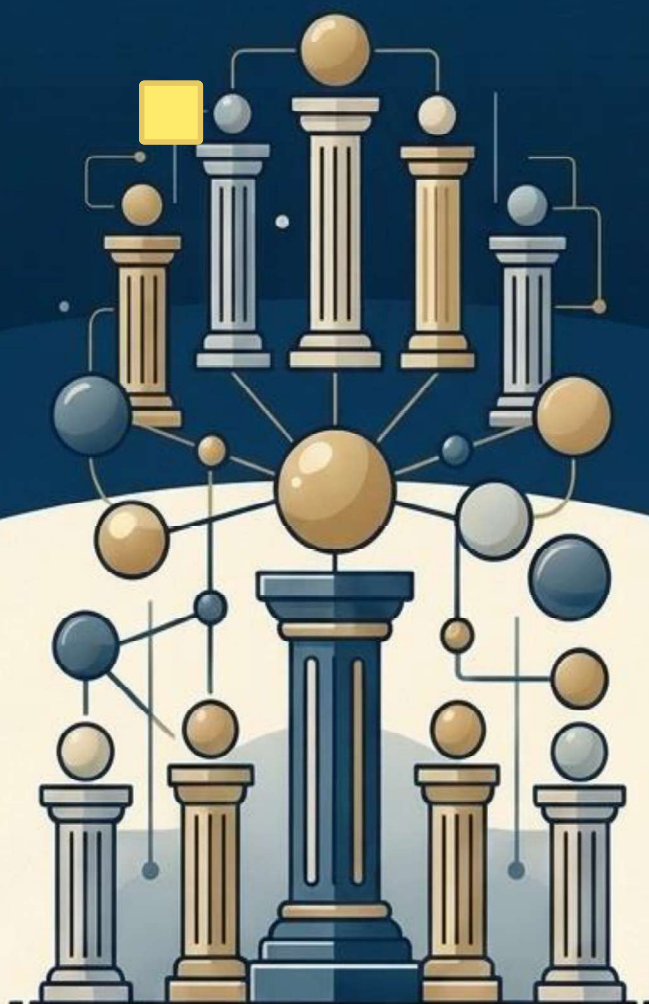




JAWAHARLAL NEHRU UNIVERSITY
INSTITUTIONAL ETHICS REVIEW BOARD

STANDARD OPERATING PROCEDURES (SOP)



IERB JNU, NEW DELHI, INDIA

EDITION: 2026
AUTHORIZED GUIDE

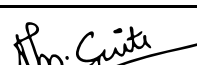
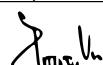
FAIRNESS • TRANSPARENCY • ACCOUNTABILITY

This SOP has been prepared in accordance with the National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR 2017, along with the Operational Guidelines for Single Ethics Review for Multicentre Research in India, an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

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1. INTRODUCTION:

Research in medical and social sciences is a systematic, scientific process aimed at understanding health and disease through the collection, documentation, and critical analysis of data, in accordance with established methodologies prescribed by recognized academic and professional bodies. Central to this process is the need for appropriate supervision and regulation by qualified professionals to ensure the highest standards of scientific integrity and ethical conduct.

To uphold these standards, Jawaharlal Nehru University (JNU) has developed the present Standard Operating Procedures (SOP) for the Institutional Ethics Review Board (IERB) and researchers. These SOPs align with the ICMR National Ethical Guidelines (2017) and provide a structured framework for the ethical review, approval, and monitoring of research involving human participants.

The IERB plays a critical role in safeguarding the rights, safety, dignity, and well-being of research participants, while also facilitating researchers in conducting ethically sound and scientifically valid studies. The Committee ensures that the fundamental principles of research ethics—autonomy, beneficence, non-maleficence, and justice—are duly upheld during the planning, conduct, and reporting of research.

As an essential regulatory and advisory body, the IERB relies on clearly defined SOPs to maintain consistency, transparency, and accountability in its functioning. This document serves as a comprehensive guide for both researchers and IERB members: it assists investigators in designing scientifically robust and ethically compliant research protocols and supports IERB members in adopting a systematic, objective approach when reviewing proposals for ethical considerations.

The accompanying forms and annexures included in this SOP facilitate standardized submission, review, documentation, and monitoring processes, thereby ensuring adherence to national and institutional ethical requirements.

2. AIM:

To review the research proposals involving human subjects to ensure that their rights are protected according to international, national, and local guidelines, as well as to monitor the progress of the study till the end, so that human rights are not violated at any point in time during research.

3. OBJECTIVES:

Our objectives are:

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be designed to produce valuable results for societal benefit, which cannot be obtained through other methods, and should not be random or unnecessary.
3. It must be based on animal testing and understanding of the disease or problem, ensuring that the expected outcomes justify the experiment.
4. Conduct should aim to prevent all unnecessary physical and mental suffering or injury.
5. No experiment should be performed if there is a known risk of death or disabling injury, unless the researchers are also subjects.
6. The risk taken should never surpass the importance of solving the scientific problem.
7. Proper preparations and adequate facilities should be in place to protect subjects from injury, disability, or death, even hypothetically.
8. Only qualified scientists should conduct the experiment, maintaining the highest skill and care throughout.
9. During the study, subjects should be free to withdraw if they reach a point where continuation seems impossible due to their physical or mental state.
10. Conversely, the lead researcher must be ready to stop the experiment at any time if there is reason to believe it could cause harm or death to the subjects.

4. Membership requirements of IERB:

Composition of an IERB

- The IERB should be composed of members from multiple disciplines.
- Adequate representation across various age groups and genders should be ensured.
- Ideally, fifty percent of the members should be non-affiliated or from outside the institution.
- The maximum number of members in an Ethics Committee should be fifteen, with at least five members present to satisfy quorum requirements.
- The EC should maintain a balance between medical and non-medical members, social scientists, and technical and non-technical members, depending on the specific needs of the institution.

The composition, affiliations, qualifications, member-specific roles, and responsibilities are:

S. No	Members of IERB	Member-Specific Roles and Responsibilities
1.	Chairperson: Non-affiliated Qualifications - A well-respected person from any background with prior experience of having served/ serving in the Ethics Committee.	Primary Responsibility: Conducting EC Meetings • The Chairperson is responsible for conducting all meetings of the EC. • The EC must meet periodically at frequent intervals to review new proposals, evaluate the annual progress of ongoing research, review SAE reports, and assess final reports of all research activities involving human participants, through a previously scheduled agenda amended as appropriate. • The Chairperson ensures that no decision remains pending beyond the timelines stipulated in the committee's SOPs (typically 3-6 months as per ICMR guidelines). • The Chairperson manages the participation of investigators invited to present or clarify proposals during meetings. • Subject experts may be invited to offer their views but must not take part in the decision-making process; their opinions must be recorded. The Chairperson oversees this process. Ratification of Minutes • Meetings are to be minuted, and these minutes must be approved and signed by the Chairperson, or a designated member of the committee. • The Chairperson ratifies minutes of the previous meeting at the start of each subsequent meeting, serving as an accountability mechanism. • All proceedings must be documented and kept in confidence; release to non-committee members is permitted only under specific circumstances. • By signing the minutes, the Chairperson authenticates the official record and assumes institutional accountability for its accuracy. • Signed and ratified minutes serve as the primary evidentiary basis during audits, regulatory inspections, or dispute resolution. Provisions for Acting Chairperson • In the absence of the Chairperson, an alternate Chairperson is elected from the members present on the day of the meeting, or the

		Chairperson may nominate a committee member as Acting Chairperson in advance. • The alternate or acting Chairperson must be a non-affiliated person and holds all the powers of the Chairperson for that meeting. • The non-affiliation requirement prevents the temporary concentration of authority in someone with a direct institutional or financial interest in research outcomes. Ensuring Quorum and Fair Decision-Making • The Chairperson is responsible for verifying quorum before any deliberation or decision begins. • Decisions must be taken by broad consensus after quorum requirements are fulfilled, to recommend, reject, suggest modification, or advise appropriate steps. • The Chairperson facilitates consensus — managing disagreement constructively, ensuring minority views are heard, and preventing premature closure of discussion. • Faith and confidence are vested in the EC and its Chairperson to manage issues of conflict of interest so that the ultimate outcome — the protection of human participants — is achieved.
2.	Member Secretary: Affiliated faculty member Qualifications - • Should be a faculty member of the institution. • Should have knowledge and experience in clinical research and ethics, be motivated, and have good communication skills • Should be able to devote adequate time to this activity, which should be protected by the institution	• Organizing and scheduling meetings: The Member Secretary is responsible for organizing all EC meetings, maintaining records, and communicating with all concerned parties. This includes issuing advance notice to members, preparing the agenda, and ensuring that research proposals are circulated to members sufficiently in advance of each meeting. • Screening and categorizing proposals: The Member Secretary or secretariat screens proposals for completeness and, depending on the risk involved, categorizes them into exemption from review, expedited review, or full committee review. This gatekeeping function determines the review pathway for each proposal and prevents incomplete or ineligible submissions from reaching the full committee. • Preparing and ratifying minutes: The Member Secretary prepares the minutes of all meetings and gets them approved by the Chairperson and all members. The signed minutes, bearing both signatures, constitute the official and legally recognized record of the committee's deliberations, decisions, and rationale. • Communicating decisions to investigators: The Member Secretary is responsible for communicating the committee's decision in writing to the Principal Investigator after each meeting. All decisions — whether approval, rejection, or request for modification — must be conveyed to the applicant within a reasonable time. • Expedited review authority: The Member Secretary, together with the Chairperson or a designated member, may conduct an expedited review for protocols presenting no more than minimal risk, such as minor deviations from approved research or studies limited to data analysis. This authority enables the EC to function efficiently between full committee meetings without compromising the integrity of the review process.

		- Record-keeping and archival: The Member Secretary is responsible for maintaining all EC records, including the constitution and composition of the EC, signed curriculum vitae of all members, SOPs, national and international guidelines, copies of all protocols, all correspondence, meeting notices and agendas, and signed minutes. All documentation must ordinarily be retained for at least 5 years after the completion of the study. - SAE reporting and management: Upon receipt of a Serious Adverse Event report, the Member Secretary forwards it to the designated reviewer and ratifies the reviewer's report along with relevant documents from the Principal Investigator at the next EC meeting. The final review opinion must be communicated to the relevant regulatory authority within 30 days of receipt of the SAE report. - Maintaining and updating SOPs: It is the responsibility of the Member Secretary and staff to maintain control over all SOPs, ensure amendments are incorporated as required, and notify all concerned users of updates. The Member Secretary also ensures that new members are oriented to the applicable SOPs, regulatory guidelines, and ICMR 2017 requirements at the start of their tenure. - Protected time and institutional support: The ICMR 2017 guidelines recommend that the Member Secretary be provided with protected time for EC work, recognizing the substantial administrative burden the role entails. Without dedicated time allocation and adequate secretarial support, the Member Secretary cannot effectively fulfil the documentation, communication, and coordination responsibilities central to the EC's functioning.
3.	Basic Medical Scientist(s) Affiliated/ non-affiliated Qualifications - Non-medical or medical person with qualifications in basic medical sciences	- The EC composition includes one to two basic medical scientists as core members of the committee. - The EC must ensure the scientific soundness of research proposals before examining their ethical implications, and the scientific evaluation must confirm the technical appropriateness of the proposed study. - Elements of review include scientific design, conduct of the study, and examination of predictable risks and potential benefits. - The EC meets periodically to review SAE reports and assess final reports of all research activities involving human participants. - A member must voluntarily withdraw from the EC while making a decision on an application that evokes a conflict of interest, which must be indicated in writing to the Chairperson prior to the review and recorded in the minutes.
4.	Clinician(s) Affiliated/ non-affiliated Qualifications – Should be individual/s with recognized medical qualifications,	- The EC composition includes one to two clinicians drawn from various institutes as core members of the committee. - The EC must evaluate the possible risks to participants, the expected benefits, and the adequacy of documentation for ensuring privacy, confidentiality, and justice issues. The clinician provides direct patient-care experience in making these assessments. - Subject experts, such as a paediatrician for pediatric conditions or a cardiologist for cardiac disorders, may be invited to offer their specialist views based on the nature of the research proposal. - The EC must protect the dignity, rights, and well-being of potential research participants and ensure that universal ethical values and

	expertise, and training	international scientific standards are expressed in terms of local community values and customs. • The EC is entrusted not only with the initial review of proposals prior to initiation but also has a continuing responsibility of regular monitoring of approved projects to ensure compliance with ethics throughout the period of the study. • A member must voluntarily withdraw from the EC while making a decision on an application that evokes a conflict of interest, which must be indicated in writing to the Chairperson prior to the review and recorded in the minutes.
5.	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	• The EC must include one social scientist, representative of a non-governmental organization, philosopher, ethicist, theologian, or a similar person as a member. • The Social Scientist member should possess qualifications and training in social or behavioral sciences, philosophy, or religious studies, and should be sensitive to local cultural, social, and moral values. A representative from an NGO working in any of these areas may also be considered eligible to serve in this role. • They undertake review of research proposals and informed consent documents with translations, undertake risk-benefit assessment from participants' perspectives, serve as participant or community representative, and bring in ethical and societal concerns. • The IEC must ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs, a responsibility the social scientist is uniquely placed to fulfil. • Members must be aware of local, social, and cultural norms, as this is the most important social control mechanism in the ethical review of research.
6.	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.	• The EC composition includes one legal expert or retired judge as a core member of the committee. • The legal expert must hold a basic degree in law from a recognized university with relevant experience. • The legal expert oversees that research protocols comply with applicable laws, regulations, and institutional policies. • The legal expert reviews the proposal, informed consent document, MoU, clinical trial agreement, regulatory approvals, insurance documents, other site approvals, and protocol-specific permissions such as stem cell committee approvals and HMSC clearance for international collaborations.
7.	Lay person(s): Non-affiliated Qualifications - • Literate person from the public or	• A lay person is a non-affiliated, literate person from the public or community who has not pursued a medical science or health-related career in the last five years, and is aware of the local language, cultural, and moral values of the community. • The inclusion of lay persons on the EC introduces a non-scientific viewpoint that reflects societal concerns and cultural sensitivities,

	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.	and their membership is mandatory in the research ethics committee. • Lay members serve as a bridge between researchers and the community, ensuring transparency in research activities and public accountability. • They provide valuable input about the comprehensibility of consent documents by prospective participants and are often the only ones providing a participant. • Preferably, the lay person should be part of the quorum at every IEC meeting, and under the New Drugs and Clinical Trials Rules 2019, their presence in the quorum for regulatory trials is mandatory.
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5. Quorum requirements for EC meetings

- A minimum of five persons is required to form the quorum, without which no decision regarding research should be taken.
- The quorum must include both medical and non-medical members, as well as technical and non-technical members.
- A minimum of one non-affiliated member must be part of the quorum.
- Preferably the lay person should be part of the quorum, and preferably the Chairperson and Member Secretary should be present in all meetings.
- The New Drugs and Clinical Trials Rules 2019 mandate the presence of a lay person for completing the quorum for regulatory trials, whereas ICMR 2017 guidelines state it is preferable but not strictly mandatory.
- For clinical trials, the five members of the quorum must specifically include a basic medical scientist (preferably a pharmacologist), a clinician, a legal expert, a social scientist or philosopher or ethicist or theologian, and one lay person from the community, as per the New Drugs and Clinical Trials Rules 2019.
- A member with a conflict of interest in a proposal being considered shall not form part of the quorum for that decision.
- Decisions must be taken by broad consensus after quorum requirements are fulfilled, to recommend, reject, suggest modification, or advise appropriate steps.
- All decisions should ordinarily be taken in meetings after going through proposals and not by the circulation of project proposals.

- A negative decision must always be supported by clearly defined reasons, and the EC may reverse a positive decision if it receives information that adversely affects the risk-benefit ratio of a study.

6. PROCEDURE FOR NOMINATING/APPOINTING IERB MEMBERS –

- The head of the institution is responsible for appointing all EC members, including the Chairperson, and the appointment letter issued to all members must specify the terms of reference.
- The head of the institution appoints the Chairperson and all committee members based on their competence, experience, and integrity; members confirm their acceptance by providing all required information for membership.
- The terms of appointment must include the duration of the term, the policy for removal, replacement, and resignation procedure, frequency of meetings, and payment of honorarium or consultancy to members and invited experts, all of which must be specified in the SOP made available to each member.
- New members are nominated when a regular member completes their tenure, when a member resigns or drops out before tenure is completed, or when the volume of proposals and frequency of review demands the appointment of additional members.
- To ensure continuity and effective functioning, only one-third of the members shall be replaced upon completion of their tenure.
- When a new member is appointed, it is advisable to induct a member in the same category as the outgoing member, and the committee must maintain representation from both men and women.
- The term of appointment may be extended for another term, and a defined percentage of members should be changed on a regular basis to ensure continuity and fresh perspectives.
- It is preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country; a substitute member may be nominated if meetings have been continuously missed by a member due to illness or other unforeseen circumstances.
- Members are appointed for a tenure of three years; they will receive voting rights in the EC only after completing the initial training on policies and guidelines.
- Upon appointment, members must submit a recently updated and signed curriculum vitae along with certificates of training in GCP, bioethics, and guidelines on biomedical and health science research.
- As per ICMR guidelines, the appointee must be informed of the rights and duties of the committee, and external members are to receive honorarium for every consultative meeting attended.

7. ETHICS COMMITTEE STRUCTURE

- The committee comprises a Chairperson, a Member Secretary, and 13 other active members who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests.
- The members should be a mix of medical and non-medical, basic science and humanities/social science/liberal arts persons, including lay persons, to represent differing points of view
- The EC can include individuals from other institutions or communities, with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community and society.
- The Chairperson of the committee should preferably be from outside the institution and not be the head of the institution, to maintain the committee's independence.
- The Member Secretary should be from the same institution and is responsible for conducting the business of the committee.
- Subject experts may be invited to offer their views — for instance, a pediatrician for pediatric conditions or a cardiologist for cardiac disorders — and based on the research area, it is desirable to include a member from specific patient groups, such as HIV or genetic disorders.
- The EC should specify in writing the authority under which the committee is established.
- All members must have undergone training in research ethics, documented by training certificates; all members must also sign a confidentiality agreement, which must be documented.

- Independent consultants may be appointed only for the review of a specific study; they will not be able to vote or participate in decision-making and may attend meetings via teleconference or video-conferencing, or by submitting their comments by email.

8. PROCEDURE OF RESIGNATION, REPLACEMENT, AND REMOVAL OF MEMBERS

Membership can be terminated under the following conditions:

- If a member resigns from the Committee.
- If a member is unable to perform their duties.
- In the event of a member's death.
- Resignation process: Any member who wishes to resign before their term ends must submit a written notice to the Chairperson. A one-month notice period is required before relief, but the Chairperson will evaluate each case to decide whether the member can leave immediately or after the notice period.
- Honorarium for members: Reimbursement of travel expenses and/or a reasonable honorarium for attending the IERB meeting will be provided only to external EC members.

9. THE TERMS OF REFERENCE FOR THE COMMITTEE AND ITS RESPONSIBILITIES

Appointment of Members

- The head of the institution appoints all EC members, including the Chairperson, and issues a formal appointment letter specifying the terms of reference, including the member's role and responsibilities, the duration of appointment, and the conditions of appointment.
- The term of EC membership is three years, extendable in accordance with institutional SOPs, with a defined percentage of members replaced on a regular basis to ensure continuity and fresh perspectives.
- Members appointed to the EC must be willing to fulfill all EC requirements and may receive a reasonable honorarium for attending meetings.

Roles and Responsibilities of the EC

- The primary responsibility of the EC is to protect the dignity, rights, safety, and well-being of all research participants, and to ensure the ethical conduct of research by the investigator team.
- The EC must ensure that universal ethical values and international scientific standards are upheld in accordance with local community values, customs, and healthcare requirements.
- At each meeting, members are required to declare any conflicts of interest to the Chairperson, and all such declarations must be recorded in the minutes.
- The EC performs its functions through competent initial and continuing review of all scientific, ethical, medical, and social aspects of research proposals, conducted in an objective, timely, and independent manner.
- The EC may review the progress reports, final reports, and adverse event or serious adverse event reports, providing recommendations on participant care and risk minimization procedures as applicable.
- The Chairperson supports the Member Secretary in all functions and must be trained in documentation and filing procedures under a confidentiality agreement.
- The EC ensures that the privacy of individuals and the confidentiality of all EC meeting documents and data are strictly protected at all times.
- The EC recommends appropriate compensation for research-related injury wherever required, and conducts monitoring visits to study sites as and when needed.
- The EC assists in developing and educating the research community within the institution — including researchers, clinicians, and students — in alignment with local healthcare requirements.
- The EC ensures that the conduct of the same or similar research by different investigators from the same institution is harmonized; replicative research is discouraged, and submission of the same research to multiple funding agencies is not accepted.

10. TRAINING OF EXISTING AND NEW MEMBERS

- The members should update their knowledge on ethics by attending various national and international conferences on ethics.
- All members must get familiarized with the guidelines of ICMR for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki, and Good Clinical Practice ICH-GCP guidelines.
- The members should update their knowledge on Ethical Guidelines for Biomedical Research on Human Participants, ICMR-2017 and New Drugs and Clinical Trial rules, 2019

11. CONFLICT OF INTEREST:

Conflict of interest (COI) arises when a secondary interest — such as financial gain or non-financial considerations (personal, academic, or political) — takes precedence over a primary interest, such as the welfare of participants or the validity of research. COI may occur at the institutional, researcher, or EC member level.

Research Institutions Must:

- Develop policies and SOPs to identify, disclose, and address COI issues at all levels of research.
- Educate staff about the nature of conflicts of interest and the procedures in place to manage them.
- Monitor research activities to ensure accuracy, objectivity, and freedom from bias.
- Refrain from interfering in the functioning and decision-making of the EC.

Researchers Must:

- Ensure that all documents submitted to the EC include a full disclosure of any interests — financial or non-financial — that may affect the conduct or outcome of the research.
- Avoid intellectual and personal conflicts by refraining from serving as reviewers for grants or publications submitted by close colleagues, relatives, or students.

Ethics Committees Must:

- Evaluate all studies submitted to them with due diligence, regardless of the source or nature of the proposal.
- Provide appropriate recommendations when COI is detected at the institutional or researcher level.
- Require all EC members to disclose their own COI by completing and signing a Confidentiality Agreement form, and take appropriate measures to recuse themselves from reviewing or deciding on protocols in which they have a conflict.
- Ensure that COI within the EC is declared and managed in accordance with the Standard Operating Procedures (SOPs) of that EC, including completing and signing the prescribed Undertaking Regarding COI form.

Conduct of Meetings:

- Members must assemble in the EC meeting room at the scheduled time. If an EC member has a conflict of interest regarding any project on the agenda, they must declare it before the meeting commences and leave the meeting room before any discussion of that project. The declaration and departure must be recorded in the minutes.

Decision-Making Process:

- An EC member must withdraw from the meeting room during the decision-making procedure for any study in which they have a conflict of interest.
- If an EC member has submitted a proposal for review by the Ethics Committee, he/she may present the proposal before the Committee and respond to queries. However, the member must not participate in the decision-making process or voting related to that proposal.
- Decisions are valid only when taken at meetings where the required quorum is present.
- Neither the Principal Investigator nor any member of the proposed study team may participate in or be present during the EC's decision-making process for that study.
- Only EC members who are present and attend the full discussion of a proposal may participate in the final decision regarding that proposal.

12. TYPES OF RESEARCH

JNU IERB will discuss and approve only the following types of research

- Observational studies
- Interventional studies
- Clinical pharmacology research
- Epidemiological studies
- Operational research
- Laboratory research
- Socio-cultural and behavioral research

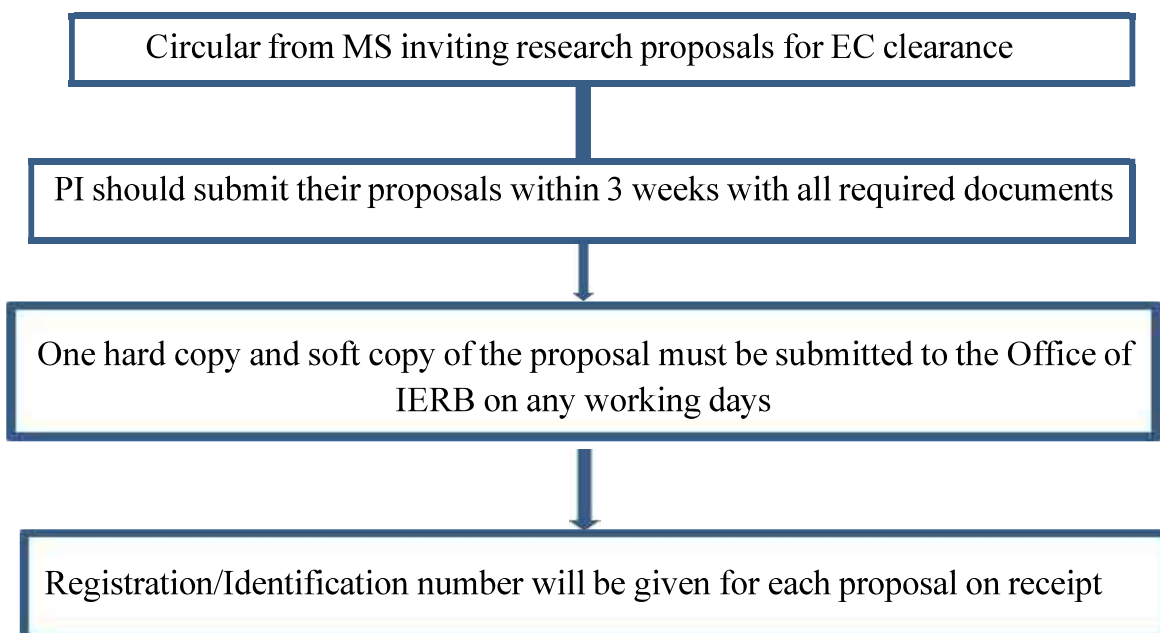
JNU IERB will not discuss and approve a Clinical Trial of a Drug and a Vaccine.

13. PROCEDURE FOR SUBMISSION OF RESEARCH:

Name of the PIs of the research proposals:

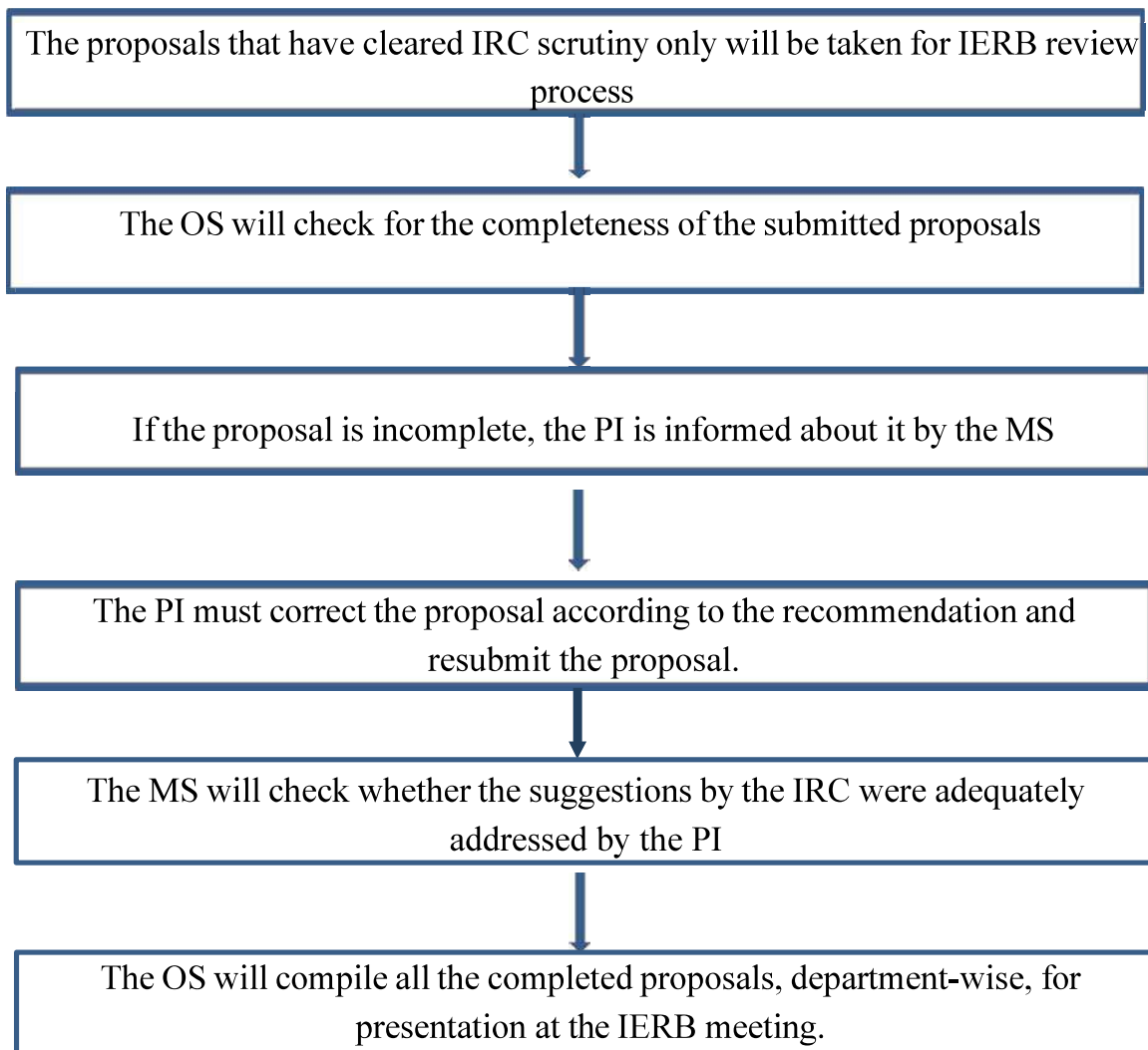
PROCEDURE:

1. For fresh research proposals:



14. INITIAL SCRUTINY OF SUBMITTED PROPOSALS

RESPONSIBILITY: The office secretary and Member Secretary of IERB. PROCEDURE:



15. PROCEDURE TO REVIEW THE SUBMITTED RESEARCH PROPOSALS

RESPONSIBILITY: All the members of IERB are responsible for carrying out this procedure.

PROCEDURE:

The proposals would reach each IERB member at least 2 weeks before the intended IERB meeting.



Each IERB members should scrutinize the proposals on ethical issues, scientific approach and technical appropriateness using the checklist.



The PI should present his research proposal in PPT to all IERB members during the notified meeting.



The IERB members should bring to the notice of PI, whatever inadequacies they have noted beforehand using the checklist.



The PI must provide convincing and appropriate answers to the doubts raised by the IERB members.



External subject expert may be asked to give expert opinion, if needed.



A decision will be taken on each proposal at the end of the meeting, with adequate time for discussion.

For multicentre research projects, the Ethics Committee shall follow the Operational Guidelines for Single Ethics Review for Multicentre Research in India, an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), as applicable.

16. REVIEW OF PROTOCOL DEVIATION / VIOLATION / NON-COMPLIANCE

Purpose:

- To give the right directions to the investigator (s) whenever there is a Protocol Deviation / Violation / Non-Compliance with the approved protocol by the EC.
- To strictly adhere to the national and international regulations/guidelines related to the Protocol Deviation / Violation / Non-Compliance from time to time.
- To provide an adequate explanation for the Protocol Deviation / Violation / Non- Compliance to the EC in context to ethical, scientific, statutory, or administrative matters

Scope:

- This SOP applies to all research protocols (pertinent to human-related research or to biological samples or secondary data) approved by the EC.

Responsibility:

- The EC office will receive all the Protocol Deviation / Violation / Non-Compliance related matters in the prescribed format by the investigator(s)
- These matters will be included in the agenda of the EC meeting for detailed explanation and further discussion.
- The EC members will review such reports and take appropriate action.

Definition: Protocol Deviation/Violation / Non-Compliance:

Any deviation/change in the protocol from the approved latest version of the protocol by the EC. Some of the examples include:

- Enrolment of study participant(s) who are not meeting the inclusion or exclusion criteria as mentioned in the approved latest version of the protocol by the EC.
- Study participant(s) received a wrong drug/inappropriate dose/improper regimen, etc., when compared to the approved latest version of the protocol by the EC.
- Any wrong methodology/procedure(s) adopted in the study other than what has been mentioned in the approved latest version of the protocol by the EC

- Use of any documents/parameters, including ICD or questionnaire or CRF, other than what has been mentioned in the approved latest version of the protocol by the EC

Detection of Protocol deviation/ non-compliance/ violation:

EC members or designated members of the DSMB who are closely monitoring the research, including its site, can detect Protocol deviations/non-compliance/violations when the research project is not conducted as per the latest approved version of the protocol. It is also taken into consideration when someone raises an issue of Protocol deviation/non-compliance/violation, which can come from the sponsor/funding agency/CRO/study site/any other sources.

Procedure for Reporting Protocol deviation/ non-compliance/ violation:

- The PI will report the Protocol deviation/non-compliance/violation in the prescribed format to the EC office within the stipulated time.
- This matter will be placed on the agenda by the Member Secretary for further elaboration and discussion at the full board EC meeting.
- The proceedings of the EC meeting will be recorded in the minutes and finally communicated to the concerned PI.

Procedures for Handling Suspected Noncompliance:

- The Member Secretary (MS) will receive any suspected Protocol deviation/non-compliance/violation and will confirm its authentication in consultation with the chairperson of EC.
- After this, the MS, in consultation with the chairperson, will put this matter on the agenda in the full board EC meeting.
- Further, the issue will be discussed at the EC meeting by all members within a week of receipt of the allegation.
- In the meeting, various records/sources pertaining to the Protocol deviation/non-compliance/violation will be further reviewed in detail with the research team. Study participants, or any other sources that are found to be relevant to the matter.
- The seriousness of Protocol deviation/non-compliance/violation is determined by the EC members, including whether it is non-serious and non-continuing, or serious and continuing, warranting investigation by the EC, or has no basis in fact. The summary of the discussion in the EC meeting will be recorded in the minutes.
- Depending on the seriousness of the protocol deviation/non-compliance/violation, the EC may decide to immediately terminate the ongoing research project.
- Wherever applicable, this issue will be communicated to the competent higher authorities, including the relevant national regulatory bodies or funding agencies, for any necessary further action.

17. PROCEDURE TO REVIEW PROPOSALS INVOLVING VULNERABLE SUBJECTS

Vulnerable persons are those individuals who 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 are in a situation that prevents them from doing so. These vulnerable persons share the following characteristics.

- Socially, economically, or politically disadvantaged and therefore susceptible to being exploited.
- Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example, people who are unconscious, differently abled.
- Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions.
- 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.

Principles of research among vulnerable populations

- Vulnerable populations have an equal right to be included in research so that the benefits occurring from the research apply to them as well.
- If any vulnerable group is to be recruited solely, the research should address the group's health needs.
- Participants must be empowered, to the maximum extent possible, to decide for themselves whether to give assent/consent to participate.
- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision-making.
- Special care must be taken to ensure participants' privacy and confidentiality, especially because a breach of confidentiality may increase vulnerability.
- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard their dignity, rights, safety, and well-being.

Stakeholders	Obligations / duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well-defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.
Ethics Committees	• During review, determine whether the prospective participants for a particular research study are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements for participation or for departures from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution, or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure the protection of the participants and the research team if the research is on sensitive topics.

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18. PROCEDURE FOR DECISION MAKING

RESPONSIBILITY: All members of EC.

PROCEDURE:

QUORUM REQUIRED:

The decision will be taken only when the quorum has at least 50% of its original strength, with the following members representing it.

1. Basic Biomedical scientist.
2. Clinician.
3. Social Scientist.
4. Lawyer and
5. A layman.

Any member having conflict of interest must inform it to the Chairperson prior to the meeting and it must be recorded in the minutes of meeting by the MS.

Members with conflict of interest must not take part in the decision making process.

Adequate time must be given for discussion of each proposal.

Only members who have participated in the discussion during the presentation by the PI are eligible to contribute in decision making process.

Consensus of members is essential for making a decision, but when consensus is impossible, decision can be arrived by resorting to voting.

Decision given may be simple and straightforward or with condition, if any, with appropriate recommendations and re-review procedure.

The decision may be,

1. Approved with or without comments/suggestions,
2. Revision with minor amendments,
3. Revision with major modifications and
4. Rejected

19. PROCEDURE FOR COMMUNICATING THE COMMENTS OF EC TO THE PI

RESPONSIBILITY: MS.

PROCEDURE:

1. The progress of all studies that have received a positive decision will be reviewed by EC from the time of the decision till the completion of the research.
2. The Progress of all the research proposals will be followed at regular intervals (at least once a year). Based on the study's needs, EC may conduct follow-up reviews at shorter intervals.
3. All the requirements and procedures for follow-up review will be similar to those of the initial and main review.
4. The comments of the EC will be communicated to the PI in writing, within 10 days of the meeting.
5. The communication of the comments will include:
 - a) Name and address of EC.
 - b) The date and place of the decision.
 - c) The name and designation of the applicant.
 - d) Title of the research proposal reviewed.
 - e) The registration number of the project.
 - f) Comments about the progress of the study/adequacy of documentation/maintenance of data sheets.
 - g) Signature of the Chairperson and Member Secretary with date.

20. PROCEDURE FOR COMMUNICATING THE DECISION OF IERB TO THE PRINCIPAL INVESTIGATOR.

RESPONSIBILITY: The member secretary will ensure that this SOP is implemented.

PROCEDURE:

1. A decision of the EC will be communicated to the applicant in writing, within 10 days of the meeting at which the decision was taken in the specified format.
2. If a proposal is approved, the EC will issue an approval certificate signed by the CP and MS. The applicants can get the same from the office of the MS, within one week of intimation, after duly signing in the prescribed form.
3. All the approvals will be valid for only three years or for the duration of the project, whichever is less.
4. The PI has to get his or her project re-approved after three years if necessary.
5. The communication of the decision will include:
 - a) Name and address of EC.
 - b) The date and place of the decision.
 - c) The name and designation of the applicant.
 - d) Title of the research proposal reviewed.
 - e) The clear identification of the protocol number
 - f) A clear statement of the decision reached.
 - g) Any advice by the EC to the applicant.
 - h) In case of conditional approval, statements/suggestions regarding the changes to be made.
 - i) In case of rejection of the proposal, reason(s) for the rejection will be clearly stated.
 - j) Signature of the MS with date.

21. CONDUCTING THE IERB MEETINGS:

RESPONSIBILITY: The Chairperson and Member Secretary will ensure that this SOP is implemented during the meetings.

PROCEDURE

1. The Member Secretary, in consultation with the Chairperson, will convene an EC meeting on a regular basis, preferably between 2 and 4 months. If the number of proposals is more, additional EC meetings can also be arranged.
2. All the proposals should reach the Member Secretary at least 3 weeks before the scheduled meeting.
3. The received proposals will be checked for their eligibility for presentation, first by the Office Secretary, followed by the Member Secretary.
4. The proposals that have cleared the IRC review only will be taken up for EC review.
5. The proposals that have fulfilled the eligibility for presentation will be sent to the Members of the EC for further scrutiny, at least 10 days before the meeting.
6. The PI, along with their Guide/Co-Guide, will be asked to make a PPT presentation of their proposal during the EC review meeting.
7. An external subject expert may be called to give their opinion if a proposal needs it. But they are not eligible to participate in the decision-making process for a proposal.
8. The deliberation and decision of the meeting have to be meticulously noted in the Minutes of the meeting by the MS, and the same should be circulated to all the Members of the EC, after CP and MS sign the Minutes of the meeting.
9. EC meetings should take place at regular intervals and at specified dates.
10. Tentative EC meeting will be conducted every three months, and this will be changed to monthly meetings depending upon the projects received for approval.
11. The PI must submit the progress of the study annually, in the prescribed format, to the EC.
12. The final report of the completed study must be submitted in the prescribed format to the EC by the PI.

22. DECISION-MAKING PROCESS ON PRESENTED PROPOSALS

RESPONSIBILITY: All IERB members are responsible for this process.

- (i) At least 5 members of the IERB must be present in the meeting, preferably having the following representation: One basic medical scientist, one clinician, one social scientist, one legal expert, and one lay person.

- (ii) Only applications that have passed the initial perusal (complete in all its aspects) will be considered for this process
- (iii) Adequate time must be given for each proposal, so that all aspects are given due importance.
- (iv) Decision must be taken in the absence of PI or other members involved in the project.
- (v) The members who have participated in the review and discussion only should participate in decision-making
- (vi) A decision should be taken on the consensus of all members. If not, it should be taken after voting.

23. RECORD KEEPING AND ARCHIVING:

1. All documents and communications of EC will be dated, filed, and archived in a secure place.
2. Only those who are authorized by the Chairperson of the IERB will have access to the various documents.
3. All the documents related to research proposals will be archived for a minimum period of 3 years in the Institute, following the completion /termination of the study.
4. No document (except the agenda) will be retained by any EC members.
5. At the end of each meeting, every member must return the CD containing all the research proposals and documents to the IERB office staff. They will archive one copy in IERB office and other copies will be destroyed after one year.
6. The following documents will be filed and archived with a proper label on the top of the file for easy identification.
 - a. Constitution and composition of IERB, JNU, New Delhi
 - b. Curriculum Vitae (CV) of all members of IERB, with records of training in Human ethics, if any.
 - c. Standard Operating Procedures of IERB, JNU, New Delhi
 - d. Annual reports
 - e. A record of all income and expenses of the IERB, including allowances and reimbursements made to the secretariat and IERB members.
 - f. The published guidelines for submission established by the IERB.
 - g. Copy of all study protocols with enclosed documents, progress reports, and SAEs.
 - h. Agendas and Minutes of all EC meetings duly signed by the CP / MS.
 - i. Copy of all existing relevant national and international guidelines on ethics and laws, along with amendments.
 - j. Copy of all correspondence with members, PI, and other regulatory bodies.
 - k. Record of all notifications issued for premature termination of a study with a summary of the reasons.
 - l. Final report of the approved projects, including microfilms, CDs and Video recordings.

24. LETTER FOR INVITING PERSONS TO BE THE CHAIRPERSON/MEMBERS OF THE IERB, JNU.

No. JNU NEW DELHI/DO/EC/20

Date:

From,
The Vice Chancellor,
Jawaharlal Nehru University,
New Delhi.

To,

Sub: consent to be Chairperson/ EC member – Reg.

Dear Sir/Madam,

We are currently forming or revamping our EC for JNU, New Delhi. To maintain high standards, please confirm your willingness to serve as Chairperson or member of our EC. Kindly send your acceptance using the provided format. An official appointment letter will be issued once we receive your acceptance.

Yours sincerely,

25. LETTER FOR WILLINGNESS TO BE CP/MEMBER OF IERB, JNU

No. JNU NEW DELHI/DO/EC/20

Date:

From,

To
The Vice Chancellor,
Jawaharlal Nehru University,
New Delhi.

.

Sub: Consent to Chairperson/EC member – Reg.

Dear Sir/Madam,

In response to your letter stated above, I affirm my willingness to be the Chairperson/Member of EC, Jawaharlal Nehru University, New Delhi.

I will carry out the responsibility entrusted upon me to maintain the high standards of EC, Jawaharlal Nehru University, New Delhi.

Please find my updated CV along with this letter.

Yours sincerely,

26. CV OF MEMBERS OF IERB, JNU

- i. Name:
- ii. Designation:
- iii. Address:
- iv. Present Affiliation
- v. Affiliation with the host institution: YES/NO
- vi. Educational qualifications:

Sl.no	Degree/Diploma/Certificate	Year	Institute/University

- vii. Experience in other academic committees:

Sl.no	Post/Position held	Year	Institute/University

- viii. Role in proposed IERB:

- ix. Additional Information (if applicable):
 - a. Chairperson of any previous ethics committee: YES/NO
 - b. Member Secretary of any previous committee: YES/NO
 - c. Member of any previous committee: YES/NO
 - d. Any other relevant information related to the human ethics

Signature

Place:

Date:

27. SECRECY UNDERTAKING BY MEMBERS OF IERB

No. JNU NEW DELHI/DO/EC/20

Date:

Name:

Designation:

Institute:

As a member of IERB at JNU, I may receive important documents containing confidential information about patients, drugs, procedures, or equipment. I will not disclose this information to any person who is not involved in EC. I also promise to return the research-related documents to the member secretary after the IERB meeting.

Signature

Place:

Date:

28. NOTIFICATION

No. JNU NEW DELHI/DO/EC/20

Date:

The competent authority is pleased to reconstitute the Institutional Ethics Review Board-JNU (IERB-JNU), consisting of the following members, for a period of three years, with immediate effect.

1. _____ Chairperson
2. _____ Member Secretary
3. _____ Basic medical scientist
4. _____ Basic medical scientist
5. _____ Basic medical scientist
6. _____ Basic medical scientist
7. _____ Clinician
8. _____ Clinician
9. _____ Clinician
10. _____ Clinician
11. _____ Social Scientists
12. _____ Social Scientist
13. _____ Social Scientist
14. _____ Legal expert
15. _____ Lay person

Director (R&D)
JNU, New Delhi.

29. INSTITUTIONAL ETHICAL COMMITTEE APPROVAL LETTER (on the IERB letterhead)

INSTITUTIONAL ETHICS REVIEW BOARD

Jawaharlal Nehru University

New Delhi-110067

Name of the Ethics Committee: IERB-JNU

IERB Ref. No.....

Title of the Project Proposal:

Principal Investigator:

Funding Agency:

Contact details:

Collaborators' Name, Address, Tel. No. &Email:

FOR OFFICIAL USE

The proposal was reviewed in a meeting held on (dt-) at (time). The following members were present.

1. Chairperson
2. Member
3. Member
- 4.....
- 5.....
- 6.....
- 7.....
8. Member Secretary

The committee resolved to:

- ☐ Approve - indicating that the proposal is approved as submitted.
- ☐ Approve- after clarifications - indicating that the proposal is approved if the clarifications requested are provided to the satisfaction of designated committee members.
- ☐ Approve after amendment/s - indicating that the proposal is approved subject to the incorporation of the specified amendments verified by designated committee members.
- ☐ Defer - indicating that the proposal is not approved as submitted but it can be re-assessed after revision to address the specified reason/s for deferment;
- ☐ Disapprove - indicating that the proposal is not approved for the reasons specified*.

Comments:

Date of Approval:

Member Secretary,
IERB, Ethics Committee

30. RESEARCH PROTOCOL PROFORMA:



INSTITUTIONAL ETHICS REVIEW BOARD

Jawaharlal Nehru University

New Delhi-110067

Name of the Principal Investigator/Supervisor:

Center of..... and School of

Detailed Information of the Study:

I.

- 1) Introduction
 - 1.1 Purpose
 - 1.2 Background & Justification
- 2) Methodology
 - 2.1 Study Design
 - 2.2 Study Objectives
 - 2.3. Study Setting (Exact place where the study will be conducted):
 - 2.4 Number of Subjects (with rationale)
 - 2.5 Minimizing Study Bias
 - 2.6 Subject Selection
 - 2.7 Inclusion/Exclusion Criteria (detail in bulleted points)
- 3) Procedure
 - 3.1 Center Readiness (Faculties available)
 - 3.2 Informed Consent
 - 3.3 Enrollment
 - 3.4 General Data Collection Requirement
 - 3.5 Specific Case Study: Longitudinal /Cross-sectional
 - 3.6 Status of withdrawal and the Plan in such a situation
 - 3.7 Conflict of interest for any other investigator(s)
- 4) Statistical Methods & Data Analysis
- 5) Data Management
- 6) Risk Analysis
 - 6.1 Potential Risk
 - 6.2 Risk Minimization
 - 6.3 Potential Benefits
- 7) Warranty
 - 7.1 Insurance
- 8) Monitoring and Auditing

8.1 Procedures and Responsibilities

8.2 Source of Funding (Name and details of funding agency; attach a copy of the sanction letter)

9) Records and Reports

10) Preliminary Publication Plan

10.1 Expected Outcome

10.2 Authorship Selection Criteria

10.3 Printing and Ancillary Publication

II. Investigator's Brochure Including Report of Prior Investigations

III. Informed Consent

IV. Insurance Statement (Wherever required):

For example, Appropriate insurance/indemnity provisions have been made to cover research-related injury or harm to participants, as per applicable regulatory guidelines. In case of any adverse event, necessary medical management and compensation will be provided in accordance with institutional policy and national regulations.

P.S. *The students are required to enclose a copy of the registration certificate and synopsis of their M.Sc./M.A./Ph.D. Research Proposal as approved by the Faculty/Supervisor/BoS.*

DECLARATION BY THE INVESTIGATOR(S)

- 1) I certify that the research proposal submitted herein is original and is not a duplication of any previously conducted or reported study, except where appropriately cited.
- 2) I undertake to obtain approval from the Institutional Ethics Review Board (IERB), Jawaharlal Nehru University, New Delhi, prior to the initiation of the research study.
- 3) I further undertake to seek prior approval from the IERB, JNU, New Delhi, for any protocol amendments or significant changes in the study design, methodology, or conduct.
- 4) I undertake to maintain complete and accurate records of all research activities and to make them available for review, audit, or inspection by the IERB or other authorized authorities, as and when required.

Signature and Name of the Research Scholar

Signature and Name of the PI

Signature and Name of the Co-PI's

Date:

Place:

31. Research Protocol Proforma for Biomedical Project only



INSTITUTIONAL ETHICS REVIEW BOARD

Jawaharlal Nehru University

New Delhi-110067

1. TITLE OF THE STUDY:
2. BACKGROUND OF STUDY:
3. SCIENTIFIC JUSTIFICATION OF THE STUDY:
4. AIMS AND OBJECTIVES:
5. REVIEW OF LITERATURE:
6. WORK ALREADY DONE (*If any pilot studies or others specify*):
7. MATERIALS AND METHODS:
 - a. Study Design:
 - b. Study Setting (*Exact place where the study will be conducted*):
 - c. Approximate Total Duration of The Study:
 - d. Number of Groups to Be Studied:
 - e. Detailed Description of The Groups:
 - f. Sample Size of Each Group (with justification/rationale):
 - g. Total Sample Size of the Study (with justification/rationale):
 - h. Scientific Basis of Sample Size Used in The Study:
 - i. Sampling Technique Used in the Study:
 - j. Inclusion Criteria:
 - k. Exclusion Criteria:
 - l. Whether Placebo Used in Study (Yes/No):
 - m. Whether Drugs/human sample(s)/Recombinant sample/Medical Devices will be used in the Study (Yes/No):
 - n. **IF DRUGS/HUMAN SAMPLE(S)/RECOMBINANT SAMPLE/ MEDICAL DEVICES USED:**
 - i. Whether the Drug/Human sample(s)/Recombinant Sample/Medical Device used is for a **Newer Indication**: YES/NO

- ii. Whether the Drug/Human Sample(s)/Recombinant Sample /Medical Device used is for the **First Time in Human Beings**: YES/NO
- iii. If used for a newer indication/first time in human beings, whether the permission is obtained from the **Drug Controller General of India (DCGI)** and/or **Institutional Bio-Safety Committee (ISBC)**: YES/NO. **Kindly attach a copy of the approval letter and also provide BioRRAP ID.**
- iv. Formulation of The Drug Used:
- v. Name of the Drug/Human sample(s)/Recombinant Sample Medical Device Used (Non-Proprietary Name, Brand Name, Company/Manufacturer's Details):
- vi. Dose/s of the Drug Used:
- vii. Frequency of the Drug Used:
- viii. Route of the Drug Used:
- ix. Duration of the Drug Used:
- x. Steps to be taken to prevent Adverse Drug Reactions (ADRs):
- xi. In Case of Severe ADR, Mode of Management:
- xii. In Case of Drug-Related Injury, Agreement of Compensation:
- xiii. Any Other Relevant Details:

o. **Parameters to be Studied** [If *quantitative data mentions the units of measurement (MUST)*]:

p. **Method(s)/Technique(s)/Instrument(s)/Reagent(s)/Kit(s) etc. Used to Measure the Quantitative Parameters Along with Their Manufacturing Source Details [MUST]:**

q. **Procedure in Detail** (*Explain, if Possible, with Flowchart*):

r. **Statistical Methods of Analysis:**

- i. Significance Level Decided Before Starting the Study:
- ii. Statistical Tests to Be Used for Data Analysis:
- iii. Software(s) To Be Used for Statistical Analysis:

8. HYPOTHESIS (*If any*):

9. REFERENCES (*Minimum 10 References in Vancouver Format Only*):

10. GIVE DETAILS OF THE FOLLOWING:

- A. Whether the Study is **multi-institutional**: YES/NO
- B. If **multi-institutional**, Whether Consent Obtained from the Department (s) Concerned:
- C. Any Extra Materials / Finance Required/Obtained to Carry Out the Study:
- D. If Yes, Write in Detail About the Source of Finance:
(Whether From Funding Agencies/Institute/Investigator (Self)/Others If Any Specify):

UNDERTAKING BY THE INVESTIGATORS

1. Full name, address, and title of the Principal Investigator.
2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial (Attach details, including Medical Council registration number, or any other statements of qualifications)
3. Name and address of all clinical laboratory facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-Investigators) who will be assisting the Investigator in the conduct of the investigations.
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Statement of Undertaking:
 - i. I certify that the research proposal submitted herein is original and is not a duplication of any previously conducted or reported study, except where appropriately cited.
 - ii. I have reviewed the protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee and regulatory approvals have been obtained.
 - iii. I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or change to the protocol without the prior review and documented approval or favorable opinion from the ethics committee for the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
 - iv. I will use the sample collected for this approved study. It will not be used for any other study without the due regulatory approval from the Ethics committee and IBSC, or any concern authority.
 - v. I agree to report all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements.
 - vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - vii. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are suitably qualified and experienced, and they have been informed about their

obligations in meeting their commitments in the trial.

- viii. I agree to maintain adequate and accurate records and to make them available for audit or inspection by the ethics committee, the Central Licensing Authority, or their authorized representatives, in accordance with regulatory provisions. I will fully cooperate with any study-related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- ix. I agree to promptly report to the ethics committee any changes in protocol and any unanticipated problems involving risks to human subjects or others.
- x. I will maintain the confidentiality of the identification of all participating subjects and ensure the security and confidentiality of study data.

Signature and Name of the Research Scholar

Signature and Name of the PI

Signature and Name of the Co-PI's

Date:

Place:

32. Participant Information Sheet (must be translated into Hindi or in the local language as well)

(for the subject/ patient recruited for the Biomedical study)



Jawaharlal Nehru University

School of

PATIENT/PARTICIPANT INFORMATION SHEET

This information sheet should contain all relevant information in simple, non-technical terms, easily understandable by a layperson, regarding your study. The information must be provided under the following headings and in the following sequence.

PART-I:

1. Title of the study.
2. Invitation to take part in the study.

Before going into the details of the study, express in a few lines regarding their freedom in participating in the study. An example is given below;

“We welcome you to take part in the study. You have the right to decide to take part or not to take part in the study. This document contains all relevant information regarding this study. It also mentions the benefits, discomfort, or possible risks involved in this study. We help you in the decision-making process by providing all relevant information about this study. Therefore, take adequate time to read what is given in this sheet, and you are free to discuss this with your friends, colleagues, family members, or your treating physicians. We are also ready to clarify any doubts in your minds regarding this study”.

3. What is the purpose of the study? _____
4. Why have I been invited to participate? _____

List out the criteria used to select the subjects for this particular study.

5. Do I have to take part? _____

Tell them that taking part in the study is entirely their voluntary decision. It can be stated as follows;

“Decision to or not to take part in the study is entirely your own choice. If you choose to be part of the study, then a copy of this sheet will be given to you for your reference and you need to sign a consent form. Even after agreeing to take part in the study, you can withdraw from the study at any point in time, without giving any reason for your decision. Doing so will not affect the standard of treatment/care you receive.”

6. What will happen to me if I take part? _____

Explain to them that they will be called for a basic physical examination / to fill out the questionnaire/ intervention/ newer treatment, or for follow-up. State how often and how long they need to come. Assure them that no injury will be inflicted on them.

7. What do I have to do? _____

Tell them whether they need to follow a certain type of lifestyle (lifestyle modification), change in their routine daily activities, or if they can continue to take their regular medication.

8. What is the drug or procedure that is being tested?

Give full information regarding the drug, viz., type, dosage, route, and frequency of administration, possible side effects, before or after food. The same way provides complete information on the procedure, viz., name, invasive or non-invasive, whether blood is withdrawn, possible side effects, and safety measures.

9. What are the alternatives to the diagnosis or treatment?

They should be informed about alternative options to the proposed diagnosis or treatment. That gives them the freedom to decide to join the research or refrain from it.

10. What are the side effects of taking part in the study?

List all the possible side effects of the drug or procedure in simple terms without using medical jargons so that the subject understands what is written. For example, instead of using terms like anemia or polycythemia, use simple terms like decreased or increased red blood cells. Some side effects may be unknown or new for that particular drug or procedure.

Therefore, advise them to contact you or any other persons involved in the research in case they notice the known side effects or any unusual manifestations. For this, they must have your address and the addresses of other investigators, along with their contact numbers.

11. What are the possible disadvantages or risks of taking part in the study?

These are for example purposes.

Pregnancy may pose a disadvantage or risk for participating in any study. So, give a clear warning as follows:

“The drug or the procedure may affect your unborn baby. Therefore, do not take part in this study if you are pregnant or planning to become pregnant during the course of the study. In case you become pregnant during the study period, inform the PI or other Investigators, who will relieve you from the study.”

Screen women subjects for pregnancy before the start of the study. Advise them to use effective contraceptive methods if they are in the reproductive age group.

The same concern should be given to male subjects. The study should not affect their sperm or sexual life.

12. What are the possible benefits of taking part in the study?

The subjects should not be lured into the study by giving exaggerated information regarding the benefits of the drug or procedure. They should not also be coerced into the study by threatening them with exaggerated disadvantages if they do not take part in the study.

Therefore, it is advisable to state that the benefits of the drug or procedure are not known at present, but this study may benefit future patients.

13. What if new information becomes available?

Any new information that becomes available during the course of study should be shared with the subject. State it as follows:

“During the course of the research, if we get any new information, it will be shared with you. Based on the new information, you can decide by yourself whether to continue the research or not. If you like to withdraw from the study, we will make all necessary arrangements to continue your medical care that have been getting from us. Withdrawing from the study will

not affect the medical care given by us. If you like to continue, then you need to sign a new updated consent form.”

14. What happens when research stops?

When the research stops due to some reason, exact reason must be told to the subject. If the sponsoring company stops sponsoring, the subject must be informed about other alternative drug/procedure.

15. What if something goes wrong?

The participants must know that there is a process/procedure in place to handle the complaints from them. Assure them that measures will be taken to rectify their grievances. If some serious events happen, the study must be stopped.

16. Will my taking part in the study be kept confidential?

Permission must be sought from the participants to get access to their medical records for necessary vital information. The information (of the subjects) that will be available during the course of the research should be strictly maintained confidentially. Though the data will be shared with other people, the identity of the subjects will not be revealed.

17. What will happen to the results of the research?

Inform them that the results of the research will be used for publishing the article in scientific journals and presentation at conferences.

18. Who is organizing and funding the research/trial?

Provide information whether the researcher is getting any financial aid from Govt., NGOs, pharmaceutical companies, organization or institution. If funded, state for what purpose the money being used viz., equipment, lab tests/ reagents, drug, procedure, etc.,

19. Did the study receive approval from the Institutional Ethics Board?

Mention that the IERB, JNU, has reviewed and approved the study. However, don't mention the individual names of the EC members who reviewed and approved the study.

20. Contact for further information:

Provide the PI's & Co-PIs' complete contact details, including mobile number/s, to the participant.

Name of the PI:

Name of the Co-PI's:

Designation:

Designation:

Contact Details:

Contact Details:

Mobile Number:

Mobile Number:

e-mail:

e-mail:

Place:

Signature of PI

Signature of PI

Details of Research Scholar:

Name:

Contact Details

Mobile Number

E-mail:

Signature of Research Scholar

(template for the social science or observational study)
(must be translated into Hindi or in the local language as well)



Jawaharlal Nehru University

School of

PARTICIPANT INFORMATION SHEET TEMPLATE

This is a template that can be adapted for your own project. Using this template is not essential – you are free to develop your own version. Participant **Information Sheets must be accessible for participants (e.g., use clear language, be clearly laid out, and not overly long)**. The PIS should generally include a University logo, if relevant.

PART I:

1. Project title
2. Invitation paragraph
3. What is the purpose of the project?
4. Why have I been invited to participate?
5. Do I have to take part?
6. What does taking part involve? (for example: your time, your active participation, etc.)
7. Are there any possible risks or disadvantages in taking part? (where relevant)
8. What are the possible benefits of taking part?
9. Will I be reimbursed for any expenses or for my time?
10. What if I want to withdraw from the project/study?
11. How will my data be looked at during/after the project?
12. What will happen to my data after the project ends?

Please explain:

- (i) if data will be destroyed after the end of the project –
for example

“At the end of the project [or 12 months after the end of funding; or after all publications have been published], all data will be deleted

(ii) if data will be retained by the PI/research team for possible future (re)use: YES/NO

13. What should I do if I want to take part?

Explain exactly how the participant should 'opt in' for the project, who they should contact and how, if there is any deadline for participating, and how and when they will be contacted.

14. What will happen with the results of the research project?

Explain what will happen to the results of the research. Will they be used in a student's dissertation or thesis? For what degree? Will they be published? As articles? A book? A policy briefing? In public engagement or knowledge exchange events? In your teaching? How can they obtain a copy of the published research? Will there be a website? A newsletter for research participants? You may not have decided on all of these matters yet, so do try and imagine all the ways you might use the research, so that you have relevant consent in the future. Do explain that they will not be identified in any report/publication unless they have given their consent for this.

15. Who is organizing and funding the research?

16. Who has approved this project?

*This research project has been reviewed and approved by IERB, JNU, and BOS of the School of
..... JNU.*

17. Your /your child's participation in this research study is voluntary. You are free to withdraw you/your child from this study at any time without penalty. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness for you or your child to participate in it, you will be notified so that you and your child can make an informed decision whether or not to continue participation in this study.

18. CONTACT FOR FURTHER INFORMATION:

PROVIDE THE PI'S & Co-PI'S' COMPLETE CONTACT DETAILS, INCLUDING MOBILE NUMBER/S, TO THE PARTICIPANT.

NAME OF THE PI:

NAME OF THE CO-PI'S:

DESIGNATION:

DESIGNATION:

CONTACT DETAILS:

CONTACT DETAILS:

MOBILE NUMBER:

MOBILE NUMBER:

E-MAIL:

E-MAIL:

PLACE:

SIGNATURE OF PI

SIGNATURE OF PI

PART II: Certificate of Informed Consent (must be translated into Hindi or the local language as well)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered to my satisfaction. I voluntarily consent to participate in this research.

willingly, under no pressure from the researcher-

- (i) agree to take part in this research, and agree to participate in ALL INVESTIGATIONS which will help acquire knowledge for the benefit of mankind,
- (ii) agree to donate my or my children's samples, such as (5 ml of blood, Sputum, or any other biological sample)

My consent explicitly does not include the disclosure of any personal information. For disclosing any such personal information obtained from the investigations/ conducted on my samples, further consent should be obtained.

I have been informed that the researchers (PI and/or her/his colleagues and Research Scholar:.....) will take my prior consent before they draw benefits from research based on participation/ my samples/my child/children's samples.

Print Name of Participant _____

Signature of Participant _____

Date _____

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ AND Thumb print of participant

Signature of witness _____

Date _____

(In case of a minor participant, kindly take consent from the parents/legal guardian in front of two witnesses)

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability, made sure that the participant understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the participant was given the opportunity to ask questions about the study, and that all questions asked have been answered correctly, to the best of my ability. I confirm that the individual has not been coerced into giving consent, and that the consent was given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Details of Research Scholar:

Name:

Contact Details

Mobile Number

E-mail:

NB: Three copies should be made, one each for (1) Patient, (2) Researcher, and (3) Institution.

(Investigators are advised to prepare the translation in simple, understandable Hindi or the local language on their own.

MINOR'S ASSENT TO PARTICIPATE IN THIS STUDY

(For ages >14 – <19 yrs): Minor should read or have the following read to him/her before signing.)

You are invited to participate in this study on: (title of study).

If you decide to participate, you will: (briefly describe what the child will do).

Your participation in this study is voluntary, and you may withdraw at any time without any penalty. If we use these results in any articles or presentations, we will not use your real name, so your identity will be protected. Please read this information and decide whether or not you want to participate in our study. Thank you so much for your help!

Name of Participant

Signature of Participant

Date

Assent obtained by:

Name:

Signature with Date

33. Conflict of Interest Disclosure Form



Institutional Ethics Review Board (IERB), JNU

Conflict of Interest (COI) Disclosure Form

1. Basic Information

Name of Individual: _____
Designation/Role (Member/Investigator/Reviewer): _____
Department/Institution: _____
Contact Details: _____
Date: _____

2. Project/Protocol Details (if applicable)

Title of Study: _____
Protocol Number: _____

3. Disclosure of Conflict of Interest

Do you have any conflicts of interest related to this study/protocol?

☐ Yes ☐ No

If yes, please specify the nature of conflict (tick all that apply):

- ☐ Financial (grants, funding, stocks, honorarium, consultancy, etc.)
☐ Professional (collaboration, competition, authorship, etc.)
☐ Personal (family, friends, relationships)
☐ Institutional (affiliation or organizational interest)
☐ Other (please specify): _____

Details of Conflict:

4. Declaration

I hereby declare that the information provided above is true and complete to the best of my knowledge.

I agree to disclose any changes in my conflict of interest status promptly to the Ethics Committee.

I understand that failure to disclose COI may lead to appropriate action.

Signature: _____

Name: _____

Date: _____

5. For Official Use (IERB)

COI Identified: ☐ Yes ☐ No

Action Taken:

- ☐ No action required
☐ Member recused from review/decision
☐ Independent review assigned
☐ Other (specify): _____

Reviewed by (Name & Signature): _____

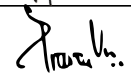
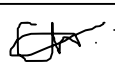
Date: _____

34. ENCLOSURES:

Ten (10) copies of the following are enclosed:

1. Covering letter signed by the PI and duly forwarded by the Dean/Chairperson.
2. Proposed Research Protocol
3. Participant Information Sheet (PIS)] in English & Hindi/local language(s)
4. Participant Informed Consent Form in English & Hindi/local language(s)
5. Conflict of Interest Disclosure Form
6. If the study is multi-institutional, a copy of the permission letter obtained from the head of the department or the competent authority, and ethical approval from all institution/s.
7. Certificate of Approval obtained from the Institutional Research Committee (IRC) (*If applicable*).
8. Case Record Form (CRF) / Questionnaire applicable to research proposal
9. Copy of Synopsis of M.Sc./M.A./Ph.D.
10. Single scanned soft copies [*In **PDF format***] of all the above.

Note: PIS and PIC form parts 1 and 2 should be translated into Hindi or local languages exactly as in English.

	Name	Designation	Signature	Date
Prepared by	Dr. Sushil Kumar Jha	Member Secretary		07/05/2026
Reviewed by	Names of IERB members	Chairperson and members		
	Prof. Amit K. Dinda	Chairperson		
	Dr. Neel S. Bhavesh	Member		01.06.2026
	Prof. Alok C. Bharti	Member		03.06.2026
	Dr. Bhaswati Das	Member	Bhaswati Das	05.06.2026
	Dr. Nemthianngai Guite	Member		04.06.2026
	Prof. D. Gopal	Member		04.06.2026
	Prof. Praveen K. Verma	Member		
	Dr. Chahat Verma	Member		
	Miss Pallavi Garg	Member		08.06.2026
Approved By	Dr. Amit K. Dinda	Chairperson		

JAWAHARLAL NEHRU UNIVERSITY
INSTITUTIONAL ETHICS REVIEW BOARD

STANDARD OPERATING PROCEDURES (SOP)

2026 EDITION

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