Standard Operating Procedure (SOP)

Institute Ethics Committee
of
Indian Institute of Technology Delhi
(IEC-IITD)

Version 01: July 2018

Version 02.01 -June 2024
Version 02.02 - November 2024 till Sept 2026

Prepared by:
Dr. Ravikrishnan Elangovan
Department of Biochemical Engineering, Indian Institute of Technology Delhi
Dr. Varsha Singh
Department of Humanities and Social Science, Indian Institute of Technology Delhi

Approved by:

Prof. Yogendra Kumar Gupta
Chairman, Institute Ethics Committee, Indian Institute of Technology Delhi

Prof. Narayanan Kurur
Dean Academics, Indian Institute of Technology Delhi

Prof. Naresh Bhatnagar
Dean Research and Development, Indian Institute of Technology Delhi

Director, Indian Institute of Technology Delhi

Preface

In India, all research proposals involving human participants, biological materials, and data in biomedical, social, and behavioral health sciences must be reviewed and approved by an appropriately constituted Ethics Committee. This is to safeguard the dignity, rights, safety, and well-being of all research participants, in line with the *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).

The Institute Ethics Committee (IEC) of IIT Delhi was established in 2017 and updated in 2024 to offer independent guidance, advice, and decisions on health or related research protocols involving human participants, as submitted by researchers from the institute. The IEC includes both scientific and non-scientific members and operates independently, ensuring unbiased reflection and decision-making.

This Standard Operating Procedure (SOP) of IIT Delhi's Institute Ethics Committee is prepared in compliance with national and international ethical guidelines. It provides clear and detailed instructions to committee members for conducting IEC activities and serves as a guide for researchers to carry out their projects ethically. The SOP helps establish a strong system of checks and balances in research involving human participants, ensuring the collection of high-quality data. Additionally, the implementation of this SOP is supported by the institutional rules and regulations of IIT Delhi. This version reflects the latest updates based on the revised ICMR guidelines.

Date:

Prof. Y K Gupta

Chairperson

IEC-IIT Delhi

Prof. Varsha Singh

Member Secretary

IEC-IIT Delhi

Contents

1.Introduction

Institute Ethics Committee, Indian Institute of Technology Delhi (IEC-IITD) has been constituted by Director, IIT Delhi to facilitate research involving human subjects following due guidelines set by the ICMR Ethical guidelines. This standard operating procedure will define the role, operation and management of the committee. This SOP details the steps and processes that should allow the IEC-IITD to enable the IIT Delhi researchers to ensure that their proposed research follows the national guidelines for ethics in human research (ICMR, 2017).

2. Objective

The objective of this SOP is to put in place an effective and consistent ethical review mechanism for health, biomedical, and social, behavioral, management, design and policy research involving human subjects and stem cells for all proposals submitted by the faculty of IIT Delhi as prescribed by the Ethical guidelines for biomedical research on human participants of ICMR (2017)[1] and National Guidelines for Stem Cell Research, 2017[2] (please see https://ethics.ncdirindia.org/ and https://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017).

3. Broad objectives and operating principles

In India and elsewhere, the process of obtaining ethics approval for human research is governed by guidelines of medical and health research (i.e., Indian Council of Medical Research). It carries the risk of creating a distinct belief that ethical guidelines for research involving human participants apply to medical sciences and are not applicable to non-medical fields which rely on human participants for research (e.g., social and behavioral sciences, management, policy, design studies). However, independent of the field of inquiry, research proposals from non-medical involve the same issue of autonomy, justice, beneficence, respect, no harm to the human participant as applied to the medical field[3].

The IEC-IITD's mandate is to evaluate and oversee proposals for ethics in research, however, the belief is that any researcher independent of their field/discipline who carries out the research on human participants owns all the ethical aspects of the research; hence the IEC-IITD's operating principle will be to collaborate with the researchers in ensuring that their proposed research aligns with the principles of Autonomy, Beneficence, Non - malfeasance and Justice. A critical part for this collaboration will be for the IEC members to perform peer review of the scientific and ethical aspects of the proposed research and for the PIs/researchers to ensure that the IEC has all the requisite information for evaluating the proposals for ethics approval. Peer review in any form carries the risks of being perceived as unfair, unjust, and evoke a range of negative responses from the PIs, however, detailed information about the processes clearly laid out in the SOP might increase trust and perception of fairness to this form of review. Adopting a two-way collaborative framework of trust and mutual respect between IEC and the PIs will ensure for the PIs that their protocol is approved on the basis of the scientific and the ethical aspects of their proposed research, and for the IEC it will ensure that they fulfill their administrative and legal responsibility for approving research that is ethical for human participation.

4. Membership requirement and appointment

The Director of IIT Delhi constitutes the IEC-IITD. Based on the guidelines set by ICMR National Ethical Guideline 2017 and Drugs Controller of India, Central Drugs Standard Control Organization, Drugs and cosmetics (Third Amendment) Rule, 2013, Ministry of Health and Family Welfare (Dept. of Health), Govt. of India. The head of the institution will appoint all members of the EC, including the Chairperson.

New members will be identified by the Chairperson according to the membership requirement after discussion in the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institute. The final decision regarding appointments of members will be taken by the Head of the Institute.

Appointment letters will be issued to each member by the head of the institution. These letters will outline:

1. The roles and responsibilities of the members within the committee.
2. The duration of the appointment.
3. The conditions of appointment, including expectations and obligations.

Notes: To maintain continuity and diversity, a defined percentage of EC members may be replaced at the end of the term. Chairperson and outside IIT Delhi Ethics Members will receive a reasonable honorarium for their participation in the meetings set by the head of the institute of IIT Delhi.

Membership requirement:

1. The duration of the appointment will be initially for a period of 3 years.
2. A member can be replaced in the event of death or long-term non availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
3. A member can receive a tender resignation from the committee with proper reasons to do so.
4. All members should maintain absolute confidentiality of all discussions during the meeting.
5. Conflict of interest should be declared by members of the IEC-IITD.

Members must be selected based on their qualifications, experience, interest, and commitment to the ethical review process. Willingness to dedicate time and effort to EC responsibilities is a prerequisite. Members to be appointed on the IEC-IITD will need to fulfill the following conditions:

1. Submit a recently signed CV.
2. Submit preferably, if available training certificates in ethics and/ or GCP [if not available at time of induction as member in the IEC, the member must submit these within 6 months of appointment].
3. Commit to ongoing training and skill updates throughout their tenure.
4. Familiarize themselves with and adhere to relevant ethical guidelines and regulations.
5. Willing to publicize his/her full name, profession and affiliation.
6. Accept the committee's Conflict of Interest (COI) policy and declare any potential conflicts when necessary. Agree to sign the Confidentiality Agreement and maintain confidentiality

regarding meetings, deliberations, research proposals, information on research participants and related matters.
7. Sign confidentiality and COI agreements.
8. Demonstrate commitment to safeguarding research participants while understanding the importance of ethical research.

5. Composition of the committee

The members will be appointed by the Director of the Institute based on their competencies and integrity and could be drawn from any public or private Institute from anywhere in the country. The Director will ensure that the IEC-IITD is established in accordance with the applicable laws and regulations of the state, country and in accordance with the principles of the communities they serve. The Director will designate and instruct the Chairperson of IEC-IITD or his representative to conduct the regular proceedings of IEC-IITD for the institute. At regular intervals, the Director will review the functioning of IEC-IITD.

IEC-IITD should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC-IITD. The number of people in an ethical committee will be around 7-15 members, with 50% of members from outside the institute as per ICMR/CDSCO guidelines.

The Chairperson of the Committee should be from outside the Institute with proven expertise in Ethical guidelines in India. The Director will select and nominate the Chairperson and Member Secretary. The IEC-IITD will be constituted by the Director in consultation with the Chairperson. The Member Secretary will be a faculty member from the Institute to conduct the business of the Committee. Other members will be a mix of medical / non-medical, scientific, social scientist, stem cell subject experts and non-scientific persons including lay public to reflect different viewpoints. The multidisciplinary nature of the committee ensures that irrespective of their field of training, and the area in which the research proposal exists, the PIs (Principal Investigators) are able to communicate their research proposal to the committee members which is inclusive of a lay person and members from non-medical background.

There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this allows members to review research proposals in the light of the national/local context, suitable training will be planned for this purpose. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. Subject experts opinions could inform the committee deliberations.

Any form of review of research has the potential to be perceived in less than positive way especially when done by a committee (as per the national guidelines) that comprises 50% of peers and colleagues, colleagues from fields other than that of the researcher, colleagues form other institution than the researchers, member from non-academic, non-clinical such as background he lay person, members who are senior or junior designation. The IEC-IITD committee members are

inducted on the basis of the national guidelines, clinicians/academicians have subject matter expertise in their areas, and all members have attested/approved to abide by the principles of ethics in research, in addition to being invited for their area expertise/roles as laid out in the SOP. The composition of the committee will allow the researcher's proposal to benefit from diverse perspectives ensuring that the concept of ethics is looked upon from various point of views (clinical-nonclinical, legal expertise-lay perspective, institute members-nonmembers, scientist-lay perspective, and multidisciplinary expertise provided by members reflecting diverse demographic of field, designations and age/gender). Following the due processes listed in the SOP, the IEC-IITD members are to provide their independent review of the research proposals for ethics approval and in case of oversights, the ethics committee shares the responsibility of ensuring ethics in research involving human participants carried out by institute researchers (PIs, faculty, students).

The composition of IEC-IITD will be as follows:

a) Chairperson
b) Vice chairperson
c) 1-2 basic medical scientists.
d) 1-2 social scientists
e) 1-2 clinicians
f) One legal expert (lawyer or retired judge)
g) One social scientist
h) One lay person from the community
i) 1 or 2 Stem cell research experts
j) Member-Secretary/alternate member secretary

One member from each academic entity regularly conducts research involving human subjects i.e., Centre for Biomedical Engineering (CBME), Department of Biochemical Engineering and Biotechnology (DBEB), Department of Humanities & Social Sciences (HUSS), Kusuma School of Biological Sciences (KSBS), Department of Electrical Engineering (EE), School of Public Policy (SPP), Department of Design (DoD), Department of Management Studies (DMS), IITD Hospital as default.

The ethics committee, with permission of chairperson, may invite subject experts from the following disciplines, the ethics committee may invite other experts from any disciplines. As and when required. The invited subject experts will not have the voting right or will not be counted for quorum.

6.Functions of IEC members

All the IEC-IITD members are expected to attend IEC-IITD meetings and participate in discussions and deliberations so that appropriate decisions can be made. IEC-IITD members will review, discuss and consider research proposals submitted for evaluation. IEC-IITD members will monitor Serious Adverse Event (SAE) reports and recommend appropriate action(s). IEC-IITD members will review the progress reports and monitor ongoing studies as appropriate; do onsite visits wherever needed; evaluate final reports and outcomes; maintain confidentiality of the documents and deliberations of Institute Ethics Committee – Indian Institute of Technology Delhi (IEC – IITD) meetings; declare any conflict of interest in writing to the Chairperson, if any, at each meeting. IEC-IITD members will participate in continuing education activities in biomedical ethics and research; provide information and documents related to training obtained in biomedical

ethics and biomedical research to the IEC-IITD secretariat; provide an updated CV when requested for by the IEC secretariat; carry out work delegated by Chairperson, Member-secretary and Alternate Member-secretary; assist Chairperson, Member-secretary and Alternate Member-secretary in carrying out IEC-IITD work as per SOPs and be updated on relevant laws and regulations.
The composition of the committee and roles of the key roles of the members are presented herewith:

6.1 Functions of Chairperson

The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals, preside over all elections as well as administrative matters pertinent to the committee's functions and representing the IEC-IITD at various meetings and forums. The chairperson will sign documents and communications related to IEC-IITD functioning, delegate his/ her responsibilities to the Vice-Chairperson in accordance with IEC-IITD SOPs. In case of anticipated absence of both Chairperson and Vice-Chairperson at a planned meeting, the Chairperson will nominate a committee member as an acting Chairperson, or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

6.2. Functions of Vice-Chairperson

To act as Chair in the absence of Chairperson and to perform all functions of Chairperson.

6.3. Functions of the Member secretary

- IEC-IITD member secretary will be responsible for the execution of the following activities:
- Receive research proposals
- Organize an effective and efficient tracking procedure for each proposal received
- Prepare, maintain and distribute study files
- Review the proposals with two members and the Chairperson if they meet the criterion for exemption and expedite review. In case of a tie between the two members, the Chairperson will serve as a tie breaker.
- Schedule and organize IEC-IITD meetings
- Prepare and maintain meeting agenda and minutes
- Maintain IEC-IITD documentation and archive them
- Sign documents and communications related to IEC-IITD functioning
- Communicate with the IEC-IITD members and applicants/ investigators
- Notify Principal Investigator regarding IEC decisions related to submitted research proposal
- Arrange for training of personnel and IEC-IITD members: Two brainstorming sessions were carried out to improve the SOP, solicit views from IEC members of nearby institutions (JNU, AIIMS), and document case studies that enabled deep reflective discussions on the challenges faced by the IEC in the deliberations.
- Organize the preparations, review, revision and distribution of SOPs and guidelines
- Provide necessary administrative support for IEC-IITD related activities to the Chairperson
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members
- Delegate various responsibilities to appropriate and authorized individuals, oversee the workings

of the staff (Project Scientist)
- Ensure adherence of IEC is functioning as per SOPs
- Prepare for audits and inspections
- Prepare and make available for scrutiny by auditors/ inspector's annual reports/ annual financial statements of the IEC-IITD
- The Member Secretary (MS) will be responsible for preparing the meeting agenda. The agenda will be:

1. Prepared at least 15 days before the meeting.
2. Circulated to all committee members via email 7 days before the meeting.

6.4. Function of Alternate Member Secretary

The Alternate Member Secretary will perform the same functions as the Member Secretary in his/her absence.

6.5. Basic medical scientist

Review of research proposals
Ensure continuing review process of Serious Adverse Events (SAE), protocol deviation progress and completion report.
Conduct benefit-risk assessment

6.6. Function of Basic scientist

Scientific and ethical review - emphasis on intervention, benefit-risk analysis, research design, methodology and statistics
continuing review process, protocol deviation, progress and completion report
drug safety and pharmacodynamics in case of clinical trials.

6.7. Function of Clinician

Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.
Thorough review of protocol, investigators brochure & all other protocol details.

6.8. Function of Legal expert

Ethical review of the proposal, translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions (NAC-SCRT, HMSC etc.) compliance with guidelines etc.

6.9. Function of Social Scientist

Ethical review of the proposal, translations.
Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
Serve as a patient/participant/ societal / community representative and bring societal concerns.

6.10. Function of Lay person

Ethical review of the proposal
Evaluate benefits and risks from the participant's perspective
Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
Assess societal aspects if any.

6.11. Secretariat

The Secretariat will be composed of the scientific officer/s, the administrative Officer/s and other administrative supporting staff. The Secretariat will support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions. All the staff of the secretariat will sign a confidentiality agreement which should be filed with the IEC-IITD.
One for technical review coordination and one administrative staff for archiving.

6.12. Independent consultants

IEC may call upon subject experts as independent consultants who may provide special review of selected research protocols, if need be. These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities; patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities. Subject expert's comments will be noted and will facilitate the IEC committee's deliberation.
The IEC-IITD was reconstructed in 2023. The composition of the reconstituted committee reflects retaining old members for continuity, inducting new members drawn from wider set of departments engineering, sciences inclusive of design, social, behavioral and management science.

7. Quorum

The following will constitute a quorum for IEC-IITD meetings:

- Chairperson/Co-Chairperson (1)
- Member-Secretary (1)
- At least one of the following (1):
  - Basic Scientist
  - Clinical Scientist
- Legal Person (1)
- Layperson or Social Scientist (1)

1. In total, a minimum of five (5) members must be present in the meeting room to constitute a quorum.
2. The quorum should include medical and non-medical/technical or non-technical members.
3. At least one non-affiliated member must be part of the quorum.
4. Preferably, the layperson should also be present during the meeting.
5. For reviewing regulatory clinical trials, quorum requirements must comply with the CDSCO guidelines.
6. Decisions made during a meeting are valid only when the quorum is met.

8.Role and responsibilities of the committee

The mandate of the IEC-IITD will be to review all research projects involving human participants including human biological materials, human biological data, and behavioral, psychological and observational research to be conducted by the Institute employees and registered students in IITD. Any research that uses data from human participation will require ethics approval prior to initiating the research. The IEC-IITD will review and approve/otherwise research proposals involving human participants with a view to safeguarding the dignity, privacy, rights, safety and well-being of all research human participants, and protect the researcher and the institute against legal risks arising from breach of ethical conduct of research. Additionally, the IIT Delhi administration may refer to other studies for the IEC's review and comment.

The Ethics committee may also examine scientific components which may have direct/indirect bearing on any ethical issue, applying the principles of bad science is bad ethics. The ethics committee has all the rights to examine the rationale.

The goals of research, however important, should never be permitted to override the health and well-being of the research participants. It will be the responsibility of the IEC- IITD to check if all the cardinal principles of research ethics including Autonomy, Beneficence, Non - malfeasance and Justice form the basis of the planning, conducting and reporting of the proposed research. For this purpose, the IEC-IITD will be responsible for scientific and ethical review of the proposals. It will look into the aspects of the informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensation wherever required. It will review the proposals before the start of the study and monitor the research throughout the study to enable reporting of amendments, adverse events, and document completion of the study through the procedures, such as annual reports, completion reports. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws governing the subject matter of the proposed research. If needed, it will have provision to call upon subject matter expertise if the proposal deals with new, emerging areas.

9.Mandate for stem cell research

The IEC-IITD is responsible for reviewing, approving, and overseeing all stem cell research activities within the institute to ensure compliance with ethical, legal, and regulatory requirements following National Guidelines for Stem Cell Research, 2017. All stem cell research projects should be submitted to the IEC-IITD for review and approval before initiation. The committee will assess the scientific merit, ethical considerations, and compliance with regulatory guidelines of each research proposal. Ethical considerations should be thoroughly assessed, including the potential benefits and risks of the research, informed consent procedures, protection of research participants' rights, and compliance with applicable ethical guidelines. The IEC-IITD may request revisions or additional information from the investigators to address any concerns or improve the research proposal.

10. IEC-IITD Office and Conduct Procedures

Member secretary will be responsible to schedule the meeting every month in consultation with Chairman and members of IEC-IITD. When the number of proposals pending review is more than 5, the member secretary can convene to a meeting earlier than planned, in consultation with the Chairperson and member's availability. The office of the member secretary will receive all the applications and maintain the record of the activities of the IEC. Complete applications will be accepted; incomplete applications will be returned to the PI within 5 workings days to avoid delays.

The member secretary will review proposals that fit the criterion of waiver/exemption and expedite review, and in the presence of two members and Chairperson approval, will approve the proposal for exemption and expedite review, member secretary will prepare the minutes of the meetings and get it approved by the Chairperson before communicating with the approval of the appropriate authority.

11. Training of Members

a) All relevant new guidelines should be brought to the attention of the members.

b) Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area. Certificate of participation should be kept in record.

12. Conflict of Interest Policy

It has been recognized that the potential for conflict of interest will always exist but a set of well-defined guidelines and definition of what constitutes as conflict of interest will enable the IEC-IITD to manage conflict issues and ensure protection of human subjects. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the proposal review or approval except to provide information requested by the Committee.

If an applicant submitting a protocol believes that an IEC-IITD member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol (e.g., competitor on a grant, funding scheme, competing lab). The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IEC-IITD member(s) in question. The committee may elect to investigate the applicant's claim of the potential conflict.

Examples of conflict-of-interest cases may be any of the following:
A member is involved in a potentially competing research program.
Access to funding or intellectual information may provide an unfair competitive advantage.
A member's personal biases may interfere with his or her impartial judgment.

13. Resignation, removal and reconstitution

The members who have resigned may be replaced at the discretion of the appointing authority for the same i.e., Director, IIT Delhi. IEC-IITD members who decide to resign must provide the Director, IITD and Chairman, IEC-IITD the written notification of their proposed resignation date at least 30 calendar days prior to the next scheduled meeting. In case of resignation, the Director, IITD would appoint a new member, falling in the same category of membership ex. NGO representative with NGO representative. Recommendations may be sought from the resigning member. Appointment may be made in the consultation with Member Secretary and /or Chairman.

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

- Conduct unbecoming for a member of the Ethics Committee
- Inability to participate in the meetings on any grounds.
- If a regular member fails to attend more than 3 meetings of IEC in a year.

- Relocate to another city or any such matter.
- The membership shall be reviewed by the IEC if the member is a regular defaulter. If deemed necessary, the IEC may decide to terminate the membership and recommend to the Director, IITD, by the Chairman IEC for necessary action.

14. Annual Activity report of the IEC-IITD for submission to the Head of the Institute

- The Member Secretary will make an annual report to brief the yearly activity report for submission.
- to the Head of the Institute with the following elements:
- Number and dates of the IEC meetings of full board.
- Number and dates of expedited review and SAE committee meetings, as applicable.
- Number and types of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year.
- **S**tatus of each study proposal whether completed / ongoing / terminated number of approvals for full board review/ expedited review with decisions**.**
- Brief details about workshops, training programs and other activities undertaken by the IEC and those attended by IEC-IITD members.
- Miscellaneous activities, if any

15. Application procedure

IIT Delhi ethics committee will be operating following Standard operating procedure (SOP) available on the IITD website. The SOP will be drawn. The Institute ethics committee will review the submissions/ proposals on the basis of the ICMR guidelines and decide to review it in one of the following three types of communications.

1. Fresh project submission for approval by IEC-IITD and exemption and expedite review requests.
2. Amendments to ongoing projects
3. Progress/closure report of approved projects

Risk assessment (Belmont report, 1979): It is believed that no form of participation in human research is completely free of risk [risk defined as the possibility of harm in any form (e.g., physical/psychological/economical/social) and reduce the wellbeing, quality of life], however clear, specific assessment of risk involved in the human research is a necessary part of the IEC-IITD's responsibility. Risk assessment would entail for instance determining whether the proposed research is carefully designed and will be executed using methods that are justified in presenting the risks to the prospective participants and allowing the prospective participants to determine the extent of risk that the participants would face by participating in the proposed research and decide whether they would like to participate in the proposed research.

Documentation

For a thorough and complete review, all research proposals should be submitted with the following documents:

a) **Name of the applicant with designation**: Pl. mention all the names of all the collaborators with their designation, and affiliation. Kindly note that the IEC approval is provided ONLY to the permanent employee of the institute, faculty/supervisor serve as the PI, students of IIT Delhi could be Co-PI's/ students listed as trainee/researcher carrying out the proposed research.

b) **Name of the Institute**/ Hospital / Field area where research will be conducted: Please mention the physical venue of the study (where the study will be carried out, data will be collected). In case of proposed research taking place in institute, company, premise other than that of IIT Delhi, provide an approval, sanction letter with your proposal, indicating that you have the permission to carry out the proposed research at the place/venue/site of the proposed study.

c) **Forwarded by the Head of the Institution /Head of the Department:** All proposals should be forwarded by the departments; the master's proposals should be forwarded by the program coordinators and the department DRCs via the Head. Supervisors requesting exemption or expedite review for Master's students proposed research (master's thesis) should append project review report or comments that might facilitate IEC in reviewing the proposal for exemption and expedite review; in case of master's program requirement (master's thesis), it is preferred that these comments are submitted with the proposal in time; project evaluation committee's comments forwarded by the program coordinator, through the DRC and the HoD, will facilitate timely review of research proposals that are part of master's program (e.g., design, cognitive science, policy, management), especially if the proposals meet the criterion for exemption or expedite, timely decision on the proposal could be made by the IEC.

d) **Protocol of the proposed research:** The protocol should carry all the necessary details that might help the IEC to understand how the proposed research reviews the scientific and ethical aspects of the proposed research proposal/protocol. It is helpful if a similar protocol submitted by the researchers has received IEC approval (approval letters could be appended). Proposals that provide a detailed research plan with sample, material, procedure, research design, analysis will facilitate evaluation of the scientific and ethical aspects of the proposal. The IEC approval is expected to convey that the proposed protocol will produce sound scientific output produced using ethical methods, procedures at every step and therefore the protocol justifies human participation in the proposed research.

e) **List of Ethical issues in the study and plans to address these issues:** The PI is encouraged to take ownership of the ethical aspect of his/her research and communicate these to the IEC in a clear and explicit manner. The expected ethical issues that might arise from the proposed research should be listed clearly and should be accompanied by the plans that are put in place to mitigate the risks. The IEC evaluation is a collaborative discussion to ensure that the ethical issues that pose a risk are discussed openly and concerns of the IEC are addressed to the IEC members to approve the protocol. The PIs should note that the IEC approval connotes that to an extent, the responsibility of potential oversights in the proposed research is shared by the IEC. Listening to the ethical issues in the study is not to reduce the odds of receiving approval of the proposal but is to help the PIs carry out the proposed work in ways that it poses the least risk and harm and maximizes benefits from the scientific and ethical aspect of research.

f) **The proposal should be submitted with all relevant enclosures** like Performa, case report forms, questionnaires, follow-up cards, etc.: The purpose of the proposal is to give requisite background of the proposed research that will facilitate the IEC deliberation and evaluation of the proposal for the scientific and ethical aspects of the proposed research. This proposal should be different from the research plan proposal that a PhD student presents to the student research committee (SRC), or the master's student presents to the project evaluation committee – the ethics proposal is intended for the IEC committee, whereas the research proposal as a requirement of a program is intended for the research committee. Kindly submit a concise proposal for the IEC for deliberation. This proposal document could include brief background, and content could justify the following aspects of the proposed work:

methods, proposed tools/materials/sample/procedure/analysis/interventions.

g) **Informed consent process, including Patient Information Sheet (PIS) and informed consent formin local language(s):** Informed consent, patient/ participant information sheet should be included, in local languages. Please refer to the guidelines of ICMR, 2017, especially in case of vulnerable population such as minors where parental consent is required. Issues related to informed consent should be explicitly stated with format of informed consent (written, verbal), and storage of informed consent. In case where informed consent is not possible, please refer to the appropriate sections and address these in the list of ethical issues.

h) For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.: PIs should provide details of pre-clinical and clinical trials from other centers within the country especially when proposed research is a part of multisite collaboration. Pilot data without IEC requires thorough deliberations, in rare case where the proposed research involves low-negligible risk (e.g., no intervention, no vulnerable population, no physiological measures, no issues with informed consent), number of observations/ data/responses for piloting an idea can be approx. 5-10. Ideally no research on human participants could be initiated without IEC approval.

i) **Curriculum vitae** of all the investigators with relevant publications in the last five years.

j) **Regulatory clearances** required.: In case the proposed research involves collaborators or have received funding from outside India with issues related to notably proposals involving sharing and/transfer of biological samples as a part of ICMR or related funding body, pl consult the ICMR guidelines for Health Ministry Screening Committee (HSMC) approval. If the proposal meets the criteria, the IEC will facilitate the process by indicating that the proposal is eligible to apply for HSMC approval.

k) **Source of funding** and financial requirements for the project.: The proposals should convey the source of funding, collaborator's/co-Is funding available for the proposed research. A funding source usually conveys the feasibility of the proposed research, including participant payment, infrastructure, lab resources especially for methods that are resource intensive. The other purpose that the information related to source of funding will serve is to allow the IEC to deliberate upon potential conflict of interests with the funders. This step protects the researcher and the institution where the proposed research is carried out. The third purpose for furnishing these details will be to ensure that participant payments, if covered under the fund available, is justifiable in terms of participant's time and engagement being fairly compensated by participation payment.

l) Other financial issues including those related to insurance: In case of proposed research involving considerable risks offering justifiable benefits to the field, the PIs should declare provisions to mitigate potential risks and harm that the participant might be exposed to via his/her participation in the proposed research.

m) An agreement to report all Serious Adverse Events (SAEs)

n) **Statement of Conflict of interests, if any**: Explicit, clear, specific statement of conflict of interests in any.

o) An agreement to comply with all national and international guidelines.

p) A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable.

q) All significant previous decisions (e.g., those leading to a negative decision or modified

protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

r) Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants.

s) For exemption and expedited review, DRC chair approval, forwarded by the HOD will facilitate the process. Proposals involving master's thesis should provide documentation of research plan/proposal approval from supervisor(s), project committee evaluation, and the master's program coordinator.

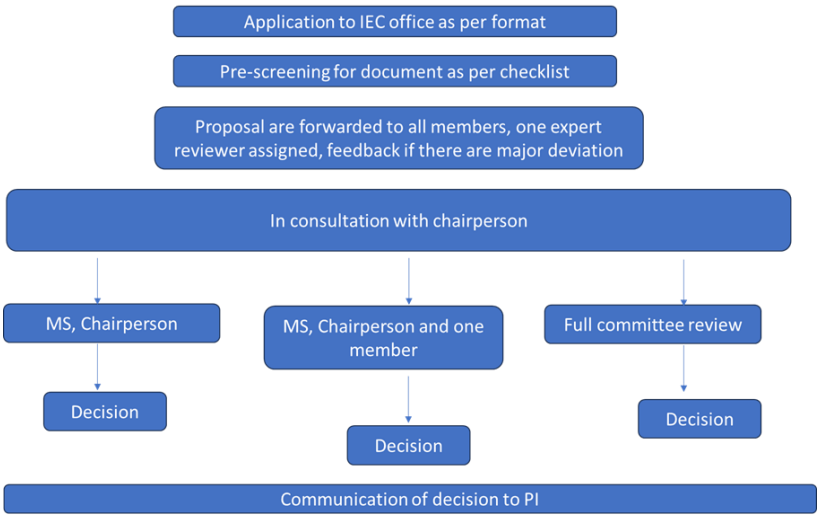
t) Any other information relevant to the study

16.Types of application

The Institute ethics committee will review the submissions/ proposals on the basis of the ICMR criterion and decide to review it in one of the following three types of communications. Please note that a full, complete proposal must be submitted for it to be reviewed and categorized in one of the three types of proposals.

- Applications for exemption from ethics review
- Application for expediated review
- Application for full committee review

The flow chart of the application procedure is shown below.



IEC- Institute Ethics Committee, **MS**- Member Secretary, **PI**- Principal Investigator.

Note:

1. PI's will be required to be present for the IEC presentation.
2. Max 8 - 10 projects will be reviewed per meeting.
3. IEC meetings will take place once a month (month end).
4. IEC will review proposals for exemption, expedite review, and full review.
5. Exemption and expedite review will be done by the member secretaries, inviting two IEC members to review.

6. Project Scientist will prepare notes for the IEC for proposal review (e.g., paperwork in place, letters of authorization, scales questionnaires, supporting documents).

16.1. Exemption from IEC-IITD Full Review

The ICMR guidelines (2017) indicate that protocols might be exempt from ethical review if the proposals fulfil certain criteria (National Institute for Research in Reproductive and Child Health, 2019). Member secretary/ Alternate Member Secretary in concurrence with Chairperson along with one or two external members can determine whether a study is qualified for exempt from ethical review based on following criteria.

Proposals with **less than minimal risk** where there are no linked identifiers that fall under this category, such as:

1.Research conducted on data available in the public domain for systematic reviews or meta-Analysis (pl. see the note the Use of Data from Public Domain. Page no. 20)

2.Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person

3.Quality control and quality assurance audits in the institution

4.Comparison of instructional techniques, curricula, or classroom management methods

5. Consumer acceptance studies related to taste and food quality.

6.Public health program by Government agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the program or monitoring (where there are no individual identifiers).

As per the ICMR guidelines, a researcher cannot decide if her/his proposal falls in the exempted, expedited or full review category. All research proposals must be submitted to the IEC. The decision on the type of review required rests with the IEC. A researcher's proposal could request exemption and expedite review providing appropriate justification for the proposal to be considered as exempt, expedited or if waiver of consent is requested.

Exempt Process

Recording the decision on Exemption in consultation with the Chairperson

If the protocol and related documents satisfy the criteria listed for Exemption request, the Member Secretary/ Alternate Member Secretary in consultation with the Chairperson along with one or two external members will review the brief summary of the project and the Exemption request. The Member Secretary records the decision and communicates the decision to the PI.

The Secretariat communicates the decision to the Principal Investigator within 30 days after the decision regarding the exemption.

•The Member Secretary informs the IEC members about the decision at the next full board meeting and minute it in the meeting notes.

•The Member Secretary / Chairperson may keep the application for review and decision regarding exemption at the next full board meeting.

• Any changes to the protocol must be brought to the notice of the IEC prior to implementation by the investigator. Any correspondence with the IEC office regarding this action should mention the allocated study number indicated at the top of this letter.

•The IEC will determine if requested protocol changes alter the risks: benefits analysis of the

study, thereby requiring a change in review or exemption category. In such cases investigators will have to resubmit the study protocol and related documents for change review process.
•Research proposals that have received exemption from review will be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.
•Once the study is complete, completion reports need to be submitted for ethics records.

Exemption: Research on Public Health Programs (ICMR, 2019)

A fundamental public health activity is to measure and monitor changes in health status, risk factors and health service access and utilization. For instance, ongoing, systematic collection, analysis, and interpretation of outcome-specific data, with the timely dissemination of these data to those responsible for preventing and controlling disease or injury. These data may be used by researchers for generating new evidence to improve programme performance, and for more generalizable application at other sites and contexts. Programme evaluation refers to the systematic application of scientific and statistical procedures for measuring programme conceptualization, design, implementation and utility; the comparison of these measurements; and the use of the resulting information to optimize programme outcomes. Evaluation research may or may not involve human participants such as health personnel, patients, community members and other stakeholders. It will also involve screening the documents and observations of various activities at different levels. Registries that are set up as part of public health programmes by a national authority may be exempted from the ethical review process if the data is de-identified. Public health program evaluation studies may be placed under the exempt from review category in specific situations where the sole purpose of the exercise is refinement and improvement of the programme or where an unspecified but large number of stakeholders are to be interviewed who are spread across large geographic areas. However, full ethical review must be carried out for programme evaluation research activities if it is clear for generalizable knowledge, to ensure scientific soundness, examine the public health value and potential harm inherent in the protocol, and the need to have permission from relevant public health authorities.

Exemption/Expedite review: Public Domain Data

(Excerpts, for full article, see Townsend, L., & Wallace, C. (2016). Social media research: A guide to ethics. University of Aberdeen, 1(16).)
'To determine whether the data you wish to access is really public, and if it is not to decide how or indeed if to proceed. The question as to whether to consider social media data as private or public comes down, to some extent, to whether or not the social media user can reasonably expect to be observed by strangers (British Psychological Society, 2013; Fuchs, forthcoming). Things to consider here are: is the data you wish to access on an open forum or platform (such as on Twitter), or is it located within a closed or private group (e.g. within Facebook) or a closed discussion forum? Is the group or forum password protected? Would platform users expect other visitors to have similar interests or issues in themselves? Does the group have a gatekeeper (or admin) that you could turn to for approval and advice? How have users set up their security settings? Data accessed from open and public online locations such as Twitter presents less ethical issues than data which are found in closed or private online spaces. Similarly, data posted by public figures such as politicians, musicians and sportspeople on their public social media pages is less likely to be problematic because this

data is intended to reach as wide an audience as possible. If the data you wish to access is held within a group for which you would need to gain membership approval, or if the group is password protected, there are more ethical issues to take into consideration.

The site or group admin will have an understanding of the social dynamics of the group and will decide how to proceed. They may wish you to seek consent from individual group members for you to access their data or offer group members the option to 'opt out' of the research (therefore you could use peoples' data unless they specify otherwise). Will you be asking questions from social media users in order to produce new data on a given subject? If so, it is vital that you are transparent about your own identity (a researcher in a university) and that responses will be used as data in your research.

Another consideration here is whether or not you might be dealing with young or vulnerable participants. You must ensure that you have taken all possible precautions to rule out the use of data by vulnerable adults (i.e. those with additional educational needs) or children (or in the case of children, seeking parental consent). Social media can often make it difficult to identify such individuals, not least because people often shield their true identities on social media platforms and discussion forums. Importantly, if data is suspected to originate from young or vulnerable individuals, informed consent cannot reliably be given so this data should be eliminated from the research. In case your research deals with vulnerable population (see ICMR, 2017 guidelines), exemption and expedite review request cannot be approved.

A final consideration is whether the data is potentially sensitive. Is the data about fairly mundane daily activities or opinions, or is there the potential to cause harm to social media users should their data be exposed to new audiences? Less sensitive data might include postings about, for example: the weather, recipes or consumer preferences. More sensitive data includes postings about, for example: criminal activity such as driving offences or the use of illegal drugs; financial problems; mental health issues and feelings of suicide; extramarital sexual activity; controversial political opinions and activism. It is your responsibility to decide whether the content is sensitive and if so to determine an ethical way of working with data. If there is risk of harm to individuals whose data you are using, you must either a) paraphrase all data which is republished in research outputs, having taken steps to ensure that the paraphrased data does not lead interested parties to the individual's online profile; b) seek informed consent from each person, should you wish to (or need to) use their data in its original form in research outputs or c) consider using a more traditional research approach where consent and confidentiality can be more safely ensured. It is also important to take these things into consideration in terms of whether you can share data sets. There might be cases where it is not straightforward to seek consent.

Exemption/expedite review: Research as course requirement

If you are carrying out research that involves collecting data from human participants, and this activity is being done for a course requirement, project requirement, dissertation requirement, these guidelines might help your supervisor/principal investigator to decide if ethical approval is needed. In the case of the master's program requirement (e.g., course work on research methods), the program coordinator's approval and the DRC's approval would be needed for request of exemption.

Doing research as a part of a course credit requirement, it is assumed that information/data from human participants is being collected as a part of a pedagogy, skill impartment (e.g., research methods such as ethnographic interview are being learned, or course on statistical methods is imparting skills that require analysis to be carried on data/responses to demonstrate knowledge skills acquired in the coursework). It is assumed that in such cases, the objective is skill acquisition and not communicating results in a scholarly avenue (if the study is intended for publication, full ethics approval is needed). In general, any form of human participation in research requires ethics approval, especially if the purpose of research activity is not related to research skills but is to communicate research findings. It is the course instructor's and supervisor's responsibility to advise undergraduate, master's and PhD students on seeking ethical approval prior to initiating research and initiate the process of seeking approval in time for timely fulfillment of the program requirement/course requirement.

It is to be noted that exemption guidelines in ICMR guidelines (2017) are to be consulted to see if your research is exempted from ethics approval. In general, the research might involve observational data about human behavior that is publicly available, unidentifiable, and anonymized, and will be used in ways that pose no-risk, no-harm, distress to the participants, and will not form the basis of publication or scholarly output. In general, if the topic is not sensitive, contentious, involving vulnerable groups (pl. see definition of vulnerable group in ICMR guidelines), it does not involve direct or indirect physiological measures, interventions, risk in any form, it might be eligible for exemption.

Proposals involving master's thesis should provide documentation of research plan approval from the master's program coordinator, the DRC approval forwarded by the HoD. Research does not involve clinical assessment and does not produce clinical data in any form. Research proposal involving program requirements (master's thesis) is to be submitted at the start of the semester in which the research outcome is to be submitted, such proposals are usually weighted by a department committee, proposals that are part of a Master's program requirement would be eligible for exempt/expedite review if they fulfill the criterion and are accompanied by the program coordinators' and the DRC's approval for request for exemption/expedite review. The program coordinators and DRC's comments on the risk involved will facilitate the IEC deliberation. Independent of the exemption/expedite request, the proposal should provide description of the study with details Patient/Participant Information Sheet (PIS), clear articulation of potential risks-benefits involved in the research and the ethics application process needs to be followed.
Master's program requirements involving research on human participants would be eligible for exemption/expedite only if the research does not involve vulnerable population listed as follows (ICMR, 2017):

- 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; or
- unduly influenced either by the expectation of benefits or fear of retaliation in case of

refusal to participate which may lead them to give consent.
Research proposals involving vulnerable participants will not be eligible for exemption and expedite review.

In such cases where the research meets the criterion for exemption (ICMR, 2017), or expedite review, your supervisor will request an exemption prior to the start of the research activity. In case the research is exempted after due consideration of your proposal, you will need to follow these guidelines for carrying out research involving human participants: research will be carried out with informed consent for participation, and the data will be obtained and stored ensuring confidentiality and anonymity.

In case the research is not exempted, it will undergo expedite review (based on the risk that it poses), if not eligible for an expedite review, the proposal will be presented for full ethics review for approval.

The request for exemption and expedite is to be made by the PI/supervisors in time for the student to initiate their work (specific IEC meetings could be scheduled in the month of May-June, and December-January to facilitate program requirements of thesis involving human participation).

16.2. Expedite review

Revised proposals

Proposals that pose minimal risk will be eligible for expedited review, revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman for expedite review. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified. To expedite review a sub- committee consisting of the member secretary, and sub-committee of scientific members maybe constituted under the Deputy chairman to review the proposal and approved by the chairperson.
PIs seeking expedite ethics approval on behalf of master's students, the proposal would be eligible for expedite review if it meets the following conditions (see listed below).
Research proposals involving vulnerable participants will not be eligible for exemption and expedite review.

Exemption-Expedite Decision:

a) In case needed, the IEC office will communicate with the PI for additional information, if needed, the IEC office could require meeting the PI, the date of meeting will be intimated to the researcher to be present for any clarifications that are required to arrive at a decision related to exemption, and on expedite review.

b) The IEC-IITD may invite member(s) of specific patient groups or other special interest groups for IEC meeting (based on requirement of research area, e.g. HIV, genetic disorders, stem cell research, social minority groups etc.) to elicit their views. Such individuals will have to sign a confidentiality agreement and declare in writing conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have the right to vote.

c) The decision will be communicated in writing. If the revision is to be made, the revised document should be submitted within a stipulated period of time as specified in the communication or before the next meeting. The member secretaries with two committee members will review the proposal, and present to the chairperson for approval of proposals that fulfill the criterion of exemption and expedite review (approval time: approx. 14 days).

16.3. Risk Assessment: Exempt, Expedite, Full review

Although ascertaining the risk involved in a proposal is a complex process requiring deliberation, in general, these guidelines might be helpful:

1. **Low/negligible risk** proposals that meet the criteria of ICMR (2017) guidelines for waiver/exemption could request for exemption.
2. **Minimal risk** proposals could request expedite review (e.g., low risk that relates to problems maintaining anonymity, confidentiality, debriefing, participant payments, or challenges in obtaining informed consent, problems of data sharing, sharing of data with other institutions).
3. The proposals that do not meet the criterion for exemption and expedite review are likely to involve **considerable risk** and will be invited for full review – these will be proposal involving interventions, vulnerable population (see definition of vulnerable population), collection of biological samples (e.g., blood, urine, tissue, cells, saliva)**,** studies involving assessment of physiological measures (e.g., pupillary response, respiration, breathing rate, heart rate, pulse rate, skin color, perspiration, blood sugar, hormones, effect of drugs, medication) using recording of neural/physiological activity (e.g., electroencephalogram, electrocardiogram, eye tracking) or brain imaging studies. PIs will be invited to present the proposal for full review, in exceptional cases (e.g., if protocol is approved in another institution.

17.Proposal Review Procedures:

The meeting of the IEC should be held at scheduled intervals of about 1-2 months.

a) The proposals will be sent to members at least 3 weeks in advance.
b) Decisions will be taken by consensus after discussions. Whenever consensus cannot be reached, voting will be done. It usually requires acceptance by more than 50% of people present in the meeting.
c) Researchers will be invited to offer clarifications if need be.
d) Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
e) The decisions will be minted, and the Chairperson's approval taken in writing.

PIs are required to submit your research project through email and hard copy of the Research Project in original along with Covering letter to the Member-Secretary, Institute Ethics Committee at Room No. 402F, Block II (Electrical Engineering Building), IIT Delhi. Internal telephone: +91-11-2659-1371.
Email: iitd_iec@iitd.ac.in .
Hard copies will be used for record keeping and soft copies will be used for all review processes.
All soft copies should be submitted in PDF format only.
Covering letter forwarded through department/center head

Check list of documents to be submitted for each application
Institute ethics application form (dually signed by all investigators)
Complete research proposal (Justification, methodology, safety, participant payment, informed consent, confidentiality and budget)

NOTE: This is NOT the same as the student's PhD, Master's proposal – kindly do not submit the same. This proposal should be concise, intended for the IEC to understand a brief background with justification for the proposed research study, including for the methodology (i.e., justification for the methods/tools employed, research design employed, variables defined will help the IEC assess the scientific and ethical aspects of the proposal – (poor research design, unstandardized tools, methods, lack of expertise available with the PI or PIs group are ways in which the participant engagement in the proposed research could be deemed unethical, harmful for the human participation), risk and safety aspects of the proposed research, confidentiality and data treatment research study.
2-3 ppt slides (Overview of study, methods flow chart and other details)
Patient information sheet (English & Hindi or local language)
Patient informed consent sheet (English & Hindi or local language as per site of the study)
CV of all the investigators
Investigators brochure (infrastructure available)
Undertaking that the study will be done in accordance with ICMR and GCP guidelines
Undertaking of who will bear the expenditure in case of injury related to study.
In the case of multi-centric study, IEC clearance of other centers must be provided.
Investigators should provide dated undertaking what they will do with the leftover sample tissue (if applicable)
Other documents as applicable
The Principal Investigator must submit the protocol forwarded by Head of The Department. All submissions should be made in the prescribed Format of the **Institute Ethics Committee** with signatures of all the investigators on the hard copy. All the pages must be numbered. The submission must be accompanied with *Participant Informed Consent Form* (PICF) and *Participant Information Sheet* (PIS), both in English and Hindi, **in a simple layman's language, in a narrative form, directed to Participant /LAR, covering all the points given on the website,** before it can be considered for placing before the Institute Ethics Committee. No research project shall be / can be started unless ethics clearance/approval is obtained. It is to note that no retrospective / post facto ethical clearance can be provided to research projects which were neither submitted nor vetted by the Institute Ethics Committee prior to initiation of the study.

17.1. Element of review

a) Scientific design and conduct of the study.
b) Approval of appropriate scientific review committees.
c) Examination of predictable risks/harms.
d) Examination of potential benefits.
e) Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.
f) Management of research related injuries, adverse events.
g) Compensation provisions.
h) If a participant volunteers to participate in the study and the study requires more than one hour

of their time, they must be compensated with a minimum of Rs 250 per hour. No study should impose a financial burden on the participant. All financial expenditures related to participant compensation should be included in the project proposal.

i) Justification for placebo in control arm, if any.
j) Availability of products after the study, if applicable.
k) Patient information sheet and informed consent form in local language.
l) Protection of privacy and confidentiality.
m) Involvement of the community, wherever necessary.
n) Plans for data analysis and reporting
o) Adherence to all regulatory requirements and applicable guidelines
p) Competence of investigators, research and supporting staff
q) Facilities and infrastructure of study sites
r) Criteria for withdrawal of patients, suspending or terminating the study

17.2. Decision-making

a) Members will discuss the various issues before arriving at a consensus decision.
b) A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises, and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
c) Decisions will be made only in meetings where the quorum is complete.
d) Only members can make the decision. The expert consultants will only offer their opinions.
e) The decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
f) In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
g) Modified proposals may be reviewed by an expedited review through identified members.
h) Procedures for appeal by the researchers should be clearly defined.

17.3. Communicating the decision

a) The decision will be communicated by the Member Secretary in writing.
b) Suggestions for modifications, if any, should be sent by IEC-IITD.
c) Reasons for rejection should be informed to the researchers.
d) The schedule / plan of ongoing review by the IEC-IITD should be communicated to the PI.

17.4. Follow up procedures.

a) Reports should be submitted annually for review.
b) The final report should be submitted at the end of the study.
c) Protocol deviation, if any, should be informed with adequate justifications.
d) Any amendment to the protocol should be resubmitted for renewed approval.
e) Any new information related to the study should be communicated.
f) Premature termination of study should be notified with reasons along with summary of the data obtained so far.
g) Change of investigators / sites should be informed.

17.5. Record keeping and Archiving

The IEC office has been maintaining records of the following since July 2021:

a) Curriculum Vitae (CV) of all members of IEC.
b) Copy of all study protocols with enclosed documents, progress reports, and Serious Adverse Events.
c) Minutes of all meetings duly signed by the Chairperson.
d) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
e) Copy of all correspondence with members, researchers and other regulatory bodies.

17.6. Policies to protect vulnerable population and compensation

A proposal that involves a vulnerable population cannot be exempted from seeking IEC approval. Protocols with **vulnerable participants** will NOT be eligible for expedited review. Individuals may be considered to be vulnerable if they fall under the following categories (ICMR, 2017).

The IEC IITD follows these rules to ensure any proposal involving a vulnerable population undergoes complete review and greater scrutiny. Policies to protect vulnerable population and compensation

As per the ICMR guidelines, vulnerable Participants are individuals whose willingness to volunteer in a clinical trial, experiment, or research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure (students, subordinates, laboratory personnel) Other vulnerable subjects include patients with unemployed or impoverished persons, patients in emergency situations, minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent (source: JIPMER).

A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence. Projects that involve a vulnerable population and special groups will be subjected to full review by all the members.

Even when a proposal requires the participation of a vulnerable population, such as children, the IEC will insist that the care taking authority (school, parents) provide written consent as a part of the IEC application.

Vulnerable persons are individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. This includes:

- Economically and socially disadvantaged individuals
- Children (up to 18 years)
- Women in special situations
- Tribals and marginalized communities
- Refugees, migrants, and homeless persons
- Populations in conflict zones, riot areas, or disaster situations
- Individuals afflicted with mental illness or cognitive impairments
- Differently abled individuals (mentally and physically disabled)
- Terminally ill individuals or those seeking new interventions after exhausting all therapies
- Individuals suffering from stigmatizing or rare diseases

- Persons with diminished autonomy due to dependency or being under a hierarchical system, who may be unduly influenced by the expectation of benefits or fear of retaliation for refusing to participate.
- 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

Responsibilities of Institutional Ethics Committees (IECs):

1. Risk and Benefit Assessment: IECs should carefully evaluate the benefits and risks of the study, examining the justification provided and risk minimization strategies.
2. Additional Safety Measures: These should be strictly reviewed and approved by IECs.
3. Informed Consent Process: IECs must ensure the informed consent process is well-documented. For research involving children aged 7 to 18 years, assent must be recorded and reconsent obtained when applicable.
4. Consent from Vulnerable Populations: Informed consent from vulnerable populations may be obtained from a Legally Authorized Representative (LAR) in the presence of an impartial witness, following a thorough explanation of the risks and benefits.

18.Guidelines for Non-medical Research

Human research in non-medical fields, not directly pertaining to health, medicine, medical interventions also involve human participation and raises ethical concerns to be addressed along different areas of concerns from an ethical point of view.
Several guidelines (document links listed) are consulted to formulate guidelines for the SOP, that might help researchers from non-medical fields to seek ethics approval.
Nuffield Council on Bioethics published the Report on The Ethics of Research Related to Healthcare in Developing Countries. https://www.nuffieldbioethics.org/wp-content/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countries-I.pdf
Following sections presents excerpts providing some of such guidelines (Horizon 2020 Program, European Union)
https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf).

Social science and humanities research — often involves working with human participants and particular methodological tools (e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions). You must therefore clarify the ethical implications of the chosen methodologies.

Example: Describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable given the methodology, what action should be taken to mitigate them? For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm (psychological, social, legal, economic, environmental, etc.) might occur, the likelihood of subjects actually incurring such harm, and the

steps that you will take to minimise them.
Research in non-medical research entailing more than minimal risk typically involves:
- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation
- deception
- risks to researcher safety
- seeking respondents through the internet/social media (e.g. using identifiable visual images or discussing sensitive issues).

Research involving vulnerable group of people, particular attention must be paid to vulnerable categories of individuals such as children, patients, people subject to discrimination, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.
If your research involves children or other individuals unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers; you must not only seek their consent, but also allow them to monitor the research.
Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.
Personal data processing method
Pseudonymisation and anonymisation are not the same thing.
'Anonymised' means that the data has been rendered anonymous in such a way that the data subject can no longer be identified (and therefore is no longer personal data and thus outside the scope of data protection law).
'Pseudonymised' means to divide the data from its direct identifiers so that linkage to a person is only possible with additional information that is held separately. The additional information must be kept separately and securely from processed data to ensure non-attribution.
This section concerns research which involves processing of personal data, regardless of the method used (e.g. interviews, questionnaires, direct online retrieval etc.). 'Personal data' means information relating to an identified or identifiable person. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Examples: name, address, identification number, pseudonym, occupation, e-mail, CV, location data, Internet Protocol (IP) address, cookie ID, phone number, data provided by smart meters, data held by a hospital or doctor.
Individuals are not considered 'identifiable' if identifying them requires excessive effort. Completely anonymised data does not fall under the data privacy rules (as from the moment it has been completely anonymised).

Following few points should be kept in mind.
1) Details of the technical and organisational measures to safeguard the rights of the research participants.
2) Details of the informed consent procedures.
3) Details of the security measures to prevent unauthorised access to personal data.
4) How is all of the processed data relevant and limited to the purposes of the project ('data

minimisation' principle)? Explain.
5) Details of the anonymization /pseudonymisation techniques.
6) Justification of why research data will not be anonymised/ pseudonymised (if relevant).
7) Details of the data transfers (type of data transferred and country to which it is transferred – for both EU and non-EU countries).
Following situations may be applicable to your research studies

Does it involve the processing of special categories of personal data (e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)?
If yes, you need:
1) Justification for the processing of special categories of personal data.
2) Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?

Does it involve processing of genetic, biometric or health data?
If yes, you need:
Declaration confirming compliance with the laws of the country where the data was collected.

Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing (such as, tracking, surveillance, audio and video recording, geolocation tracking etc.) or any other data processing operation that may result in high risk to the rights and freedoms of the research participants?
If yes, you need:
1)opinion of the data controller on the need for a data protection impact assessment:
2) Details of the methods used for tracking, surveillance or observation of participants.
3) Details of the methods used for profiling.
4) Risk assessment for the data processing activities.
5) How will harm be prevented, and the rights of the research participants safeguarded? Explain.
6) Details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.

Does your research involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?
You should explain:
1) Details of the database used or of the source of the data.
2) Details of the data processing operations.
3) How will the rights of the research participants be safeguarded.
4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)?
5) Justification of why the research data will not be anonymised/ pseudonymised (if relevant)
If yes, you need:
1) Declaration confirming lawful basis for the data processing.
2) Permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).
3) Informed Consent Forms + Information Sheets + other consent documents (opt in processes, etc.). (if applicable).

Does your research involve publicly available data?
If yes, you need:
1) permission by the owner/manager of the data sets (e.g. social media databases) (if applicable) for this purpose
2) Confirm that the data used in the project is publicly available and can be freely used for the project.

19. Checklist for vulnerable group input

Researchers

- Acknowledge the vulnerability of participants and implement additional safeguards to ensure their protection.
- Provide a rationale for including or excluding vulnerable populations in the study.
- Address conflicts of interest (COI) to avoid compromising participant welfare.
- Establish clear and detailed procedures (SOPs) to maintain a balanced benefit-risk ratio.
- Ensure that participants are competent to provide informed consent.
- Obtain consent from a legally authorized representative (LAR) when participants lack the capacity to consent.
- Respect the right of participants to withdraw or dissent at any stage of the study.
- Obtain necessary permissions from relevant authorities when working with institutionalized individuals, tribal communities, or other groups requiring additional oversight.
- Conduct research in compliance with applicable guidelines and regulations.

Ethics Committees (ECs)

- Assess whether prospective participants in a research study are considered vulnerable during the review process.
- Evaluate the justification provided for the inclusion or exclusion of vulnerable populations.
- Ensure that COI does not compromise participant safety or reduce potential benefits.
- Carefully assess potential risks and benefits to participants, recommending risk mitigation strategies where needed.
- Propose additional safeguards, such as frequent reviews, monitoring, or site visits.
- Limit the review of proposals involving vulnerable populations to the full committee. It is recommended to include representatives from the specific populations in deliberations where possible.
- Take special care when evaluating research involving individuals with mental illness or cognitive impairment. Require researchers to justify exceptions to standard participation requirements and minimize deviations from established guidelines. These exceptions should be explicitly outlined in the Informed Consent Document (ICD).

Sponsors

- Sponsors, including government agencies, institutions, or pharmaceutical companies, must justify the inclusion of vulnerable groups in research protocols and ensure measures to safeguard their well-being.
- Facilitate monitoring processes and implement mechanisms for quality assurance (QA) and quality control (QC).
- Ensure that adequate provisions are in place to protect both participants and researchers, particularly in studies involving sensitive topics.

The following annexures apply to some sections of vulnerable participants (source: AIIMS Deoghar). These checklists should be filled in by the principal investigator and should be reviewed by IEC members.

Annexure 1: Checklist: Requirements for research involving children

Annexure 2: Checklist: Requirements for research involving pregnant women & fetuses

Annexure 3: Checklist: Research involving cognitively impaired adults

Annexure 4: Checklist-Research involving students, employees or residents.

Annexure 5: Checklist: Considerations for genetic research

Annexure 6: Checklist: Procedure for CCTV footage data collection *(This section is under progress and will be updated soon)*

Research involving parts/ material/ tissues from deceased individuals?

Annexure 1: Checklist: Requirements for research involving children

Principal Investigator:

Study Title:

Checklist	YES	NO	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Have appropriate studies been conducted on animals and adults justified?			
If No: Is the lack of appropriate studies conducted on animals and adults justified?			
Will older children (12-18) be enrolled before younger (7-12) ones?			

Is permission of both parents or guardian necessary?			
If Yes: Are conditions under which one of the parents may be considered: not reasonably available" described?			
If Yes: Are the conditions acceptable?			
Will efforts be made to ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects' privacy and the confidentiality of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a risk factor which has implications for other family members? (for example, genetic risk, HIV infection, Hepatitis C)			
If Yes: Are adequate mechanisms in place to deal with other members of the family?			
Should parents be required to be present during the conduct of the research?			
(Are proposed subjects to be very young? Are the procedures involved painful? Must participants stay overnight in the hospital when they otherwise would not have to?)			

Annexure 2: Checklist: Requirements for research involving pregnant women & fetuses

Principal Investigator:

Study Title:

When research involves pregnant women or fetuses:

Checklist	YES	NO	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing			

potential risks to pregnant women and fetuses			
Is the risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
Any risk is the least possible for achieving the objectives of the research			
Is the woman's consent or the consent of her legally authorized representative obtained in accord with the informed consent provisions, unless altered or waived in accord with ICMR guidelines,2017.			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child.			
If the research involves children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission will be obtained in accord with the provisions of subpart D			
Will any inducements, monetary or otherwise, will be offered to terminate a pregnancy?			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;			
Do the individuals engaged in the research will have no part in determining the viability of a fetus.			
THIS RESEARCH INVOLVES NEONATES AFTER DELIVERY	**YES**	**NO**	**NA**
Are scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates			
Is the individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child			
Will any inducements, monetary or otherwise, will be offered to terminate a pregnancy			
Do individuals engaged in the research will have part in any decisions as to the timing, method, or procedures used to terminate pregnancy			
Individuals engaged in the research will have no part in determining the viability of a fetus			

A. Fetuses of uncertain viability	**YES**	**NO**	**NA**
Does the research hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research;			
OR The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research			
The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			
B. Nonviable fetuses	**YES**	**NO**	**NA**
Vital functions of the fetus will not be artificially maintained			
There will be no risk to the fetus resulting from the research			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
The legally effective informed consent of both parents of the fetus will be obtained in accordance with subpart A of 45 CFR 46, except that the waiver and alteration provisions of and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph			

If the response to any of above is No, the research is not approvable by the IEC at this time. See section 3.

SECTION 3
THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

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

B. The secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) to determine either:

1) That the research in fact satisfies the conditions of 45 CRF, as applicable, or

2) The following:

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

2.2 The research will be conducted in accord with sound ethical principles; and

2.3 Informed consent will be obtained in accord with informed consent provisions of 45CFR 46 subpart A and other applicable subparts, unless altered or waived in accord with 45 CFR or (d).

Annexure 3: Checklist: Research involving cognitively impaired adults

Principal Investigator:

Study Title:

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject	**YES**	**NO**	**NA**
The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject.			
More than minimal risk to subjects is presented by monitoring procedures that is likely to contribute to the subject's well-being.			
The risk is justified by the anticipated benefit to the subjects.			
The relation of anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.			
The proposed plan for the assessment of the capacity to consent is adequate.			
Assent is required of (All Subjects/All Subjects capable of being consulted/ None of the subjects).			
The consent document includes a signature line for a legally authorized representative.			
2.Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject	**YES**	**NO**	**NA**
The proposed plan for the assessment of the capacity to consent is adequate.			
The objectives of the trial cannot be met by means of studying subjects who can give consent personally.			
The foreseeable risks to the subjects are low.			
The negative impact on the subject's well-being is minimized and low.			
The trial is not prohibited by law.			
Subjects have a disease or condition for which the procedures in the research are intended.			
Subjects will be particularly closely monitored.			
Subjects will be withdrawn if they appear to be unduly distressed.			

The proposed plan for the assessment of the capacity to consent is adequate.			
Assent is required of (All Subjects/All Subjects capable of being consulted/ None of the subjects).			
The consent document includes a signature line for a legally authorized representative.			

Annexure 4: Checklist-Research involving students, employees or residents.

Principal Investigator:

Study Title:

Does the employer or supervisor of the research subject need to be aware of the research project?	**No**	**Yes**
Is there a letter of support and/ or internal services checklist?	**No**	**Yes**
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	**No**	**Yes**
Have the risks to subjects been minimized?	**No**	**Yes**
Have subjects been assured that participation is voluntary (no signs of coercion)?	**No**	**Yes**
Have subjects been assured that confidentiality will be protected or maintained?	**No**	**Yes**

Annexure 5: Checklist: Considerations for genetic research

Principal Investigator:

Study Title:

Checklist	**YES**	**NO**
Will the samples be made anonymous to maintain confidentiality?		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counseling being offered?		

20. Frequently asked questions (FAQs)

General Q & A (for social/behavioral/management sciences and policy, design studies)
We have compiled these Q&A for some of the common queries, these are guidelines subject to final approval and verification by IIT IEC committee.

Content:

20.1. General Information

Q1. How do I determine if my study requires an ethical approval from the Institute ethics committee?
Any study, project, thesis work, consultancy research work that involves human participants to provide any type of data, sample, interventional drug/implant etc. When in doubt you can reach out IEC office bearer: iitd_iec@iitd.ac.in **(iitd [underscore]iec [at]iitd[dot]ac[dot] in).**

Q2. What is the basis of the ethics committee to review research proposals involving human subjects?
Research involving human participants are regulated by Nuremberg convention and Indian guidelines given by ICMR https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx

Q3. My research does not involve any medical procedure, medication, or clinical population, why do I have to follow the ethics process that is governed by the Indian Council of Medical Research (ICMR)?
The standard assessment of risk in research proposal across countries entails assessing the proposal for physical harm, distress, discomfort, and lowered health due to research participation. Guidelines set by the medical council enable assessing the risk involved in the research proposal.

Q4. My study does not involve any biomedical data or physiological data or data related to disease/disorders, medicines, why do I need ethical approval? Or
My study involves survey/ interviews or qualitative methods that pose no harm, why do I need ethical approval?
Any kind of research involving human participants (including data collected for social behavioral, cognitive, psychological sciences, management sciences, studies in design, policy, AI and technology studies) requires institute ethical approval.
The basic assumption is that the research involving human participants should be assessed for ethical consideration for potential risk to physical and mental health to the participant. Currently, all Indian research involving human subjects are mandated to follow guidelines approved by ICMR.
Q5. When conducting qualitative research, like interviews, where the researcher might need

to adapt the approach for better participant comprehension, is it still necessary to submit a detailed protocol for ethics approval?

Ethics approval is crucial for all research, including qualitative studies. While a qualitative study may involve some flexibility in how questions are phrased during the interview, a well-developed plan is still essential.

1. The ethics committee needs to understand the overall research goals, interview topics, and potential risks to participants. Minor adjustments to wording or phrasing to improve comprehension are expected and don't require an amendment to your protocol.
2. However, if the changes you make are significant and affect the core aspects of your research, like purpose, hypothesis, or key interview questions, it's important to submit an amendment to your approved protocol with the ethics committee.

If you're unsure whether a change requires an amendment, don't hesitate to contact the ethics committee office. They can provide guidance and help you navigate the process if contacted in a time-bound manner.

Q06. What is the validity of the certificate issued by the IEC?

The certificate's validity is one year from the date of issuance. If your work extends beyond that period, you must inform the IEC office about the extension with a progress report and ask for an extension and renewed certificate with a new validity date. Alternatively, you can provide a closure/completion report to conclude the project.

Q07. How long does the ethical review process typically take?

The ethical review process usually takes around 4-6 weeks from the date of submission of a complete proposal. However, this timeframe may vary depending on the project's complexity and the committee's workload. The ethics committee is scheduled to meet every month in the third week. You should submit the application before the 5th of the month to be considered for the upcoming ethics committee review (end of the month). You are advised to prepare your application well in time and take 2 months to turn around the cycle for your application.

20.2. Application Process

Q8. In studies involving survey/interviews what are the best practices to follow in the application?

A Participant information sheet (PIS) should be included in the application.

1. It should be simple language for the participant to understand.
2. It should be in a language the participant can understand.
3. If the participant is illiterate, then oral consent can be obtained, i.e., the interviewer reads out the PIS and seeks oral confirmation for participation. Audio recording of the oral consent must be stored for verification.
4. A copy of informed consent signed by the participant and interviewer should be provided to the participant.
5. The privacy of the participant must be protected and raw data identifying the participant should be only with the principal investigator or co-principal investigators.
6. Tentative time required from the participant should be mentioned in the PIS
7. Any kind of financial inducement for the study participant is not recommended, only time and travel compensation are permissible. In the past, the studies compensating participants up to 150 – 200 Rs/hr. have been approved. This information should be included in the

PIS.

8. If the participants are from a particular organization, appropriate approval from the representative is required to conduct the study.
9. PI are advised to avoid recruiting participants who are the students enrolled in the courses, this helps in retaining participant's freedom to not participate in the research.

For surveys, interviews and qualitative ethnographic studies.

1. A list of questionnaires should be submitted along with the application.
2. If the questionnaire is part of a known study protocol, it should be referenced and provided in the application. Advisable to attach author's permission to use the material and ensure there is no copy right violations.
3. In case of ethnographic studies, list of questions and topics, variables/themes to be covered should be provided in the application. It is advised that this list of questions, themes, variables, constructs are related to the research hypothesis, and questions. This ensures that the participant's time is utilized in a suitable manner.

Q9. I would like to learn about the ethics application, review process and best practices in studies involving human subjects. Can you suggest some online resources?

You can learn about ethics applications, review processes, and best practices in studies involving human subjects through various online resources:

1. **ICMR-National Institute of Epidemiology (ICMR-NIE)** offers online courses on their website (https://nie.gov.in/icmr_sph/Online-courses.html).
2. **NPTEL-NOC IITM** has a YouTube channel with a playlist titled "Ethics Review of Health Research" that covers relevant topics.
3. **Sangath e-Learning Platform** provides both free and paid courses related to research ethics and human subjects, which can be accessed through their website.

These resources should give you a comprehensive understanding of the ethics application process and best practices in studies involving human subjects.

Q10. Who should be Principal investigator in projects involving human subjects? Can thesis students or project staff be the principal investigator?

All research involving human participants should be supervised by a regular/permanent faculty in the institute. Students and contractual staff (including post doc fellows) work under the guidance of a supervisor/mentor/host who is a permanent employee of the institute and the same could serve as a PI for the proposal with the student/staff as co-PI. Documents related to the study must be maintained for at least 5 years, and the legal obligation to maintain these documents rests with the permanent faculty supervisor.

Q11. Can I start my study after submission of the Ethical application?

The study can only start after the approval obtained from the IEC IIT Delhi. This is to protect the rights of the participant and institute reputation. The institute's ethics committee carries out the responsibility of assessing research proposals involving human participants to ensure that the research carries no risk and no harm to the participants.

Q12. I have started a pilot study; should I seek ethical approval after initiating a pilot study?

The ICMR 2017 guidelines state the definition and aim of a pilot study, A pilot study, project or experiment is a small-scale preliminary study conducted in order to evaluate feasibility,

time, cost, adverse events and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project.' Tentatively, the sample size of the participants in pilot study is less (N < 10). **Ethical approval cannot be given to a pilot study in absence of a research proposal** (research query and design) submitted with justification for, and usage of pilot data in the full proposal.

Q13. I collect data involving human participants; however, the data is in the form of video, audio format, do I need ethics approval?
Yes, any form of data provided by human participants will require ethics approval to ensure that research insights obtained based on this data abide by ethical principles of research.

Q14. My research involves data related to human participants, but I cannot seek their consent to participate in the research (e.g., data collected via social media)
Firstly, Check the terms of use and data privacy policies of the social media platform where you're collecting data. Some platforms may restrict certain types of research.
Secondly, employ robust anonymization techniques to ensure data cannot be re-identified back to individual participants.

1. Even without individual consent, seeking ethical approval for your research is crucial. Ethics committees can help you navigate the complexities of using non-consented data and ensure your study minimizes risks to participants.
2. Clearly explain in the proposal as well as the ethics committee why obtaining individual consent isn't feasible in your case.
3. Demonstrate that your research design minimizes risks to participants. Anonymization and data security measures are vital. Furthermore, clearly explain the potential benefits of your research, both for the participants and for society as a whole.

Q15. IEC members provided feedback for a research proposal. How many days does the PI have to submit a response to avoid a new application?
The PI has 25 days to respond to feedback/suggestions after the IEC meeting discussion. If they do not respond within 25 days, they will need to start the fresh application process.

Q16. What should I do if there are changes or amendments to my research project after receiving approval from the IEC?
Any changes or amendments to the approved research project must be promptly communicated to the IEC office for review and approval. This includes modifications to the study protocol, participant recruitment procedures, data collection methods, or any other significant changes that may impact ethical considerations (Refer Annexure 4 on IITD ethics website).

20.3. Exemption and Expedited Review

Q17. What are the criteria for submission of application under expediated review?
The criteria for submission of an application under expedited review:

1. Involves non-identifiable specimens and human tissue obtained from sources like blood banks, tissue banks, and leftover clinical samples.
2. Involves non-identifiable clinical documentation materials such as data, documents, and

records.
3. Involves modifications or amendments to an approved protocol, including administrative changes, correction of typographical errors, or changes in researcher(s).
4. Represents a revised proposal that was previously approved through expedited review, full review, or continuing review of an approved proposal.
5. Involves minor deviations from the originally approved research that pose no or minimal risk.
6. Includes progress or annual reports where there is no additional risk, such as activities limited to data analysis.
7. The expedited review of Serious Adverse Events (SAEs) or unexpected Adverse Events (AEs) will be conducted by the SAE subcommittee.
8. For multicenter research where a designated Ethics Committee (EC) has approved the proposal, a participating Ethics member may review participating center-specific information and modifications in the study proposal through a full committee meeting/expedited review depending on the importance of local consent-related issues involving specific to the center.
9. Relates to research conducted during emergencies and disasters (refer to Section 12 of the ICMR Ethical Guidelines, 2017).

Q18. What are the criteria for submission of application under review exemption?
The criteria for submission of an application under review exemption:
1. Research is based on data in the public domain, systematic reviews, or meta-analyses.
2. Observation of public behavior or information recorded without linked identifiers, as long as it doesn't harm the interests of the observed person.
3. Quality control and quality assurance audits within the institution.
4. Comparisons among instructional techniques, curricula, or classroom management methods.
5. Consumer acceptance studies related to taste and food quality.
6. Public health programs conducted by government agencies.

For a detailed understanding of studies exempt from review, refer to the National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51, Table 4.2. This includes program evaluations aimed at refining and improving programs or monitoring without individual identifiers.

20.4. Working with Specific Participants
Q19. What are the best practices if the participant is minor?
1. Informed Consent- Since minors cannot give consent themselves, a legally authorized representative (usually a parent or guardian) must provide informed consent.
2. Assent Form- Whenever possible, the minor should also be involved in the decision-making process by obtaining their assent (agreement) to participate. This involves explaining the study in a way that they can understand and respect their wishes.

Q20. What are the best practices if the participant is from a vulnerable group?
Here are the best practices when working with participants from vulnerable groups, along with the justification based on the ICMR guidelines from 2017:
1. Justification for Inclusion: Researchers need to clearly explain why it's necessary to involve vulnerable populations in the research. This justification ensures that the potential benefits of the research outweigh any risks or burdens for these participants.

2. Informed Consent: The informed consent process for vulnerable populations should be adapted to their specific needs and understanding. This may involve using simpler language, providing additional information sheets, or involving a trusted intermediary to explain the research in a culturally appropriate manner.
3. Training and Cultural Competence: Ensure researchers and staff working with vulnerable participants receive training on ethical considerations, cultural competence, and sensitivity. This training helps them understand and navigate the unique challenges and needs of vulnerable populations.
4. Handle Sensitive Topics Carefully: Handle sensitive topics with care and respect for cultural sensitivities. Use appropriate language and methods to collect data without causing distress to participants.
5. Include Distress Protocol: Incorporate a distress protocol into your research proposal. This protocol outlines steps to be taken if a participant from a vulnerable group experiences distress during the study, ensuring their well-being is prioritized.

The justification for these best practices can be found in Section 6 of the ICMR guidelines from 2017, which provides detailed guidance on research involving vulnerable populations. This section emphasizes the need for additional safeguards, adapted consent processes, cultural sensitivity, and justification for including vulnerable participants in research studies.

20.5. Online Data Collection

Q21. What are the best practices for conducting online based data collection?

1. Clear and Accessible Information: The informed consent document should be clear, concise, and accessible to participants. This might involve offering different formats (e.g., online document, downloadable PDF) and using easy-to-understand language.
2. Online Consent Process: Ensure the online consent process is user-friendly, and participants can easily understand what they're agreeing to. This could involve including options to review information and ask questions before consenting.
3. Implement strong data security measures to protect participant information collected online. This might involve encryption, password protection, and secure storage practices.
4. Data Minimization: Collect only the data that is essential for research study. Avoid collecting unnecessary personal information.
5. Transparency about Data Use: Clearly explain to participants how their data will be used, stored, and shared in the informed consent document. Offer options for participants to withdraw their data if they wish.

Depending on the specific nature of your research, you may need to consider additional ethical issues. If you have any doubts, consult with an ethics committee or a professional familiar with research ethics.

20.6.Multi-Institute Research

Q22. What are the best practices if there are other institutes from India involved?

1. Establish a formal agreement (MoU) between all participating institutions outlining roles, responsibilities, data sharing agreements, and conflict resolution mechanisms.
2. Establish a clear data sharing agreement between all institutions. This should specify data ownership, access rights, storage practices, and publication arrangements.
3. Implement robust data security measures to ensure the privacy and confidentiality of

participant data across all institutions.

General Guidelines for IIT Delhi Institutional Ethics Committee

1. Multiple Studies in One Proposal

- Combining multiple studies within a single proposal is **not allowed**. Each study must have its own distinct research question and methodology to be considered for ethical approval.
- This ensures clarity in research objectives and prevents overlap or confusion in ethical oversight.

2. Pilot Studies

- Pilot studies must be limited to **fewer than 10 participants** ($N < 10$). Ethical approval for a pilot study will only be granted with the submission of a **complete research proposal**, clearly justifying the need for the pilot and explaining how its data will inform the full study.
- This ensures that even preliminary studies follow rigorous ethical standards and contribute meaningfully to the larger research effort.

3. Presence of Principal Investigator (PI) or Co-Investigator (Co-I)

- The PI or Co-I must be present in person during IEC meetings when their study is under review. This is essential for providing clarifications, addressing concerns, and ensuring the committee has all necessary information to make an informed decision.
- In-person participation fosters direct communication and enables a more thorough review of ethical considerations.

4. Amendment Submissions

- Amendments to ongoing studies will be accepted only **once per semester**. Researchers must notify the IEC ahead of time about any intended changes or modifications.
- Limiting amendment submissions ensures better oversight and prevents frequent disruptions to the ethical review process.

5. Expedited or Exemption Review

- Only the **Member-Secretary and Chairperson of the IEC** is authorized to determine whether a study qualifies for expedited or exemption review. PIs cannot make this determination on their own.

6. Post-Hoc Ethical Approval

- **Post-hoc or retrospective ethical approval is strictly prohibited**. If ethical approval is overlooked or missed, the **academic officer** must be immediately informed, and corrective actions will be taken.
- **Rationale**: Prohibiting post-hoc approval maintains the integrity of the ethical review process, ensuring all studies meet ethical standards before data collection begins.

7. Research Site Restrictions

- A PI cannot designate an academic course as a research site. Similarly, **students' contingency funds** cannot be listed as a source of research funding.
- This prevents conflicts of interest and ensures the appropriate allocation of resources for research purposes.

8. Commercialization of Research Results

- Any **commercialization** of results generated from research conducted under the IEC's purview is **not permitted**.
- This protects the academic integrity of research and ensures results are used for the public good, not for private financial gain.

9. Brand Identification in Research

- Identifying specific **brands** in research proposals is not allowed, unless it is directly relevant to the research question and justified by the PI.
- This avoids any potential biases or conflicts of interest that could arise from brand association.

Ethical Issues Related to Campus Community Data Collection

10. Data Collection Approval

- Researchers must obtain **IEC approval** before initiating any data collection involving the IIT Delhi campus community.
- **Pre-approval Requirements**:
    - Proposals must include details on the data collection method, type of data being collected, duration, and potential risks to participants.
    - Only full-time IIT Delhi faculty members are authorized to collect, store, and process sensitive data (e.g., CCTV footage, biological samples). Students or part-time faculty must be supervised by a full-time faculty member.
    - Principal Investigators (PIs) must submit a **signed undertaking** to the IEC, stating that data will be used solely for research purposes and handled according to ethical guidelines.

11. Data Security and Privacy

- All collected data, including **CCTV footage, urine, garbage, and blood samples**, must be securely stored in **password-protected databases**.
- **Restrictions**:
    - Sharing raw data (e.g., video footage, biological samples) with students, staff, or external parties is strictly prohibited without IEC approval.
    - Any incidents involving data mishandling or security breaches must be reported immediately to the IEC. **Compromised data** will be excluded from the study.

12. Informed Consent

- **CCTV Data Collection**:
    - **Signage**: Clear and prominent signage must be displayed near CCTV cameras (40 inches tall x 46 inches wide) communicating the following:
        1. **Purpose** of the study.
        2. **Duration** of data collection.
        3. **An opt-out mechanism** for individuals wishing to be excluded from footage analysis.
- **Biological Samples**:
    - Written **informed consent** must be obtained from participants before collecting **urine, garbage, or blood samples**.
    - Consent forms should be in **layman's language** and clearly explain the study purpose, data collection method, risks/benefits, and participant rights (including the right to withdraw at any time).

13. Special Considerations for Biological Samples

- **Urine and Garbage Sample Collection**:
    - Collection must be made in a way that respects the **privacy** and **dignity** of individuals and households. Researchers must avoid identifying individuals through their samples without explicit consent.
- **Blood Sample Collection**:
    - Blood samples should be collected only by **qualified medical professionals** and in compliance with national **bioethical standards**.
    - Participants must be fully informed of any potential risks or benefits.

21. References

1. Padma T, Thakur K, Hazam RK, Vishwakarma MB. *INDIAN COUNCIL OF MEDICAL RESEARCH 2011. 29th, General, Assembly, Tokyo, Japan, Kong. WMA Declaration of Helsinki -Ethical Principles for Medical Research Involving Human Subjects. WMA Gen Assem [Internet]. 1975 [Cited 2017 Nov 28]; Available from: Http:/.*; 2017. http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf.
2. Jotwani G, Sharma A, Kumar V. *National Guidelines For Stem Cell Research, Indian Council of Medical Research & Department of Biotechnology*.; 2017. http://icmr.nic.in/guidelines/Guidelines_for_stem_cell_research_2017.pdf.
3. Lindorff M. Ethics, ethical human research and human research ethics committees. *Aust Univ Rev*. 2010;52:51+. https://link.gale.com/apps/doc/A222252903/AONE?u=anon~609ba3d1&sid=googleScholar&xid=747b8d51.