Standard Operating Procedures
Version 2

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

2026

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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.

Prof. Y K Gupta
Chairperson
IEC-IIT Delhi

Prof. Varsha Singh
Member Secretary
IEC-IIT Delhi

Contents

Glossary

CDSCO	Central Drugs Standard Control Organization
CTRI	Clinical Trial Registry of India
DCGI	Drugs Controller General of India
HMSC	Health Ministry's Screening Committee
IC	Informed Consent
ICMR	Indian Council of Medical Research
IEC-IITD	Institutional Ethics Committee of Indian Institute of Technology Delhi
LAR	Legally Acceptable/Authorized Representative
MoU	Memorandum of Understanding
PI	Principal Investigator
PIS	Participant Information Sheet
SAE	Serious Adverse Event
SOP	Standard Operating Procedures

Objective

The objective of this SOP is to ensure the effective functioning of the Institutional Ethics Committee (IEC-IITD) for human research. This SOP aims to establish a quality and consistent ethical review mechanism for proposals involving biomedical, health-related, non-health, social, and behavioral research reviewed by the Committee.

This SOP is framed in accordance with applicable national regulatory and ethical frameworks, including but not limited to:

- *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (ICMR, 2017);
- *National Ethical Guidelines for Biomedical Research Involving Children* (ICMR, 2017) (hereinafter collectively referred to as the ICMR Ethical Guidelines, 2017);
- *Drugs and Cosmetics Act, 1940* and *Drugs and Cosmetics Rules, 1945* (including subsequent amendments); *New Drugs and Clinical Trials Act and Rules, 2019*; and
- *National Guidelines for Stem Cell Research, 2017*.

The Institutional Ethics Committee of the Indian Institute of Technology Delhi (IEC-IITD), located at Delhi–110016, is registered with the Drugs Controller General of India (DCGI), the Department of Health Research (DHR), and the Office for Human Research Protections (OHRP), National Institutes of Health (NIH). For the purposes of this document, the Committee shall be referred to as **IEC-IITD**.

IEC-IITD adheres to all relevant national and international ethical guidelines and best practices governing human research. As it is not feasible to address every ethical scenario within a single SOP, matters not explicitly covered herein shall be guided by the ICMR Ethical Guidelines, 2017, as mandated under the New Drugs and Clinical Trials Rules, 2019.

Guiding Principles: Ethics Beyond the Medical

Human research in India has largely evolved through the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, which may create the perception that ethical principles apply primarily to medical sciences. However, irrespective of discipline, all research involving human participants raises the same fundamental ethical concerns related to autonomy, beneficence, non-maleficence, justice, respect, and the obligation to avoid harm.

Roles and Responsibilities of IEC-IITD

A. The IEC-IITD, is mandated to conduct scientific, administrative, and ethical review of all research projects involving human participants conducted by Institute employees and registered students of IIT Delhi. This includes research involving human biological materials and data, as well as behavioral, psychological, and observational research conducted at the Institute. Any research that uses data derived from human participation requires prior ethics

approval before initiation. Research involving human samples or materials likely to affect human health also falls under the purview of the IEC-IITD.

B. The IEC-IITD reviews and approves, requires modifications to, or disapproves research proposals involving human participants with the objective of safeguarding the dignity, privacy, rights, safety, and well-being of research participants and potential participants. The Committee also examines issues related to data safety and storage and seeks to protect both the researcher and the Institute from legal risks arising from breaches of ethical conduct in research. In addition, the Committee examines compliance with all applicable regulatory requirements, ethical guidelines, administrative and financial rules, and relevant laws governing the proposed research.

C. The Ethics Committee may examine scientific components and research methodology to the extent that they have a direct or indirect bearing on ethical issues, guided by the principle that *poor scientific design constitutes poor ethics*. In this context, the Committee has the authority to examine the scientific rationale of the proposed research where necessary.

D. The IEC-IITD ensures that the goals of research do not override the health and well-being of research participants. It is the responsibility of the Committee to verify that the cardinal principles of research ethics—Autonomy, Beneficence, Non-maleficence, and Justice—form the basis for the planning, conduct, and reporting of research. For this purpose, the Committee reviews aspects such as the study site, inclusion and exclusion criteria, informed consent process, risk–benefit assessment, equitable distribution of burdens and benefits, and provisions for compensation wherever applicable.

E. The IEC-IITD reviews research proposals prior to the commencement of the study and monitors approved research throughout its duration. This includes review of amendments, reporting and assessment of adverse events, and oversight through periodic submissions such as annual progress reports and completion or closure reports. Where required, the Committee may seek subject matter expertise, particularly for proposals involving new or emerging areas of research, and continues to ensure compliance with applicable guidelines, regulations, and laws throughout the study lifecycle.

F. In accordance with the procedures outlined in this SOP, members of the IEC-IITD shall conduct independent ethical review of research proposals. In cases of oversight, the Committee collectively shares responsibility for ensuring ethical conduct in research involving human participants carried out by Institute researchers, including faculty, staff, and students.

Composition of the IEC-IITD

A. The Institutional Ethics Committee, Indian Institute of Technology Delhi (IEC-IITD), shall be constituted in accordance with the *ICMR Ethical Guidelines, 2017* and the *New Drugs and Clinical Trials Act and Rules, 2019*. The Committee shall be multidisciplinary and multi-sectoral in composition, with independence and competence as its core principles.

B. The IEC-IITD shall comprise approximately 7–15 members, with at least 50% of the members drawn from outside the Institute**,** as prescribed under the applicable national guidelines. The Chairperson of the Committee shall be from outside the Institute and shall have demonstrated expertise in ethical guidelines in India. The Chairperson and the Member Secretary shall be nominated by the Director of the Institute, and the Committee shall be constituted by the Director in consultation with the Chairperson. The Member Secretary shall be a faculty member of the Institute and shall conduct the administrative business of the Committee.

C. The Committee shall include a balanced mix of medical and non-medical members, including scientific, social science, clinical, legal, stem cell research, and non-scientific expertise, along with representation from the lay public. Adequate representation with respect to age, gender, community, and social background shall be ensured to safeguard the interests and welfare of diverse sections of society. Members shall be familiar with local, social, and cultural contexts relevant to the research under review, and suitable orientation or training shall be arranged where required.

D. Where necessary, the IEC-IITD may invite subject matter experts to provide inputs on proposals involving specialized or emerging areas of research, such as clinical trials, genetic disorders, or other domain-specific studies. Invited subject experts shall participate only in an advisory capacity and shall not have voting rights or be counted towards quorum.

The IEC-IITD shall comprise the following members:

a) Chairperson and Vice-Chairperson (external to the Institute)
b) One to two basic scientists
c) One to two social scientists
d) One to two clinicians
e) One legal expert (lawyer or retired judge)
f) One lay person from the community
g) Two stem cell research experts (one internal and one external)
h) Member Secretary / Alternate Member Secretary (internal to the Institute)

Within this composition, the IEC-IITD shall, to the extent feasible, include representation from academic units that regularly conduct human participant research, namely the Humanities and Social Sciences (HUSS), School of Public Policy (SPP), Centre for Biomedical Engineering (CBME), Department of Biochemical Engineering and Biotechnology (DBEB), Kusuma School of Biological Sciences (KSBS), Department of Management Studies (DMS), and the IIT Delhi Hospital (with permanent representation), to reflect the disciplinary diversity of proposals reviewed by the Committee.

Authority under which IEC-IITD is constituted

The Director has appointed the members of the IEC-IITD based on their competence, integrity, and relevant experience, and such members may be drawn from public or private institutions across the country. The Director designates the Chairperson of the IEC-IITD, or an authorized representative, to conduct the regular proceedings of the Committee.

भारतीय प्रौद्योगिकी संस्थान दिल्ली

INDIAN INSTITUTE OF TECHNOLOGY DELHI

समन्वय अनुभाग / COORDINATION SECTION

No. IITD/ICDN/1/27/2025(1)/451639 Date: 01.10.2025

Sub: - Institute Ethics Committee (Human Research)

In supersession of Notification No. IITD/ICDN/1/27/2025(1)/444308(11) dated 12.09.2025 and No. IITD/ICDN/1/27/2025(1)/448179 dated 22.09.2025, the Director is pleased to re-constitute the following committee for the year 2025-26, to look into the Ethical Consideration involved in Research on Humans: -

S. No.	Name and Affiliation	Designation/Role in the Committee
1.	Dr. Yogendra Kumar Gupta (Professor), Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP) President, AIIMS - Jammu, and Former President AIIMS Bhopal	Chairperson
2.	Dr. Renu Saxena (Professor), Senior Director, Path and Lab Medicine and Head, Hematopathology Medanta, The Medicity	Vice Chairperson
3.	Dr. Jatinder Singh Arora, General secretary, National Thalassemia Welfare Society	Member
4.	Dr. Eqbal Hussain (Professor), Faculty of Law, Jamia Millia Islamia	Member
5.	Dr. Vikas Manchanda (Professor), Department of Microbiology, Maulana Azad Medical College	Member
6.	Dr. B. S. Tiwari, Retired Army / Ex IITD Safety Officer	Member
7.	Dr. Sujata Mohanty (Professor), Stem Cell Facility, All India Institute of Medical Sciences	Member
8.	Dr. Mahesh Sagar, Head, Hospital and Health Services, Indian Institute of Technology Delhi	Member (Ex-Officio)
9.	Dr. Sayed Yasmeen (Chief Medical Officer), Hospital and Health Services, Indian Institute of Technology Delhi	Member
10.	Dr. Upasna Sharma (Associate Professor), School of Public Policy, Indian Institute of Technology Delhi	Member
11.	Dr. Deepti Abbey (Assistant Professor), Kusuma School of Biological Sciences, Indian Institute of Technology Delhi	Member
12.	Dr. Pramod Ratnakar Khadilkar (Associate Professor), Department of Design, Indian Institute of Technology Delhi	Member
13.	Dr. Anup Singh (Professor), Centre for Biomedical Engineering, Indian Institute of Technology Delhi	Member
14.	Dr. Shilpi Minocha (Assistant Professor), Kusuma School of Biological Sciences, Indian Institute of Technology Delhi	Member
15.	Dr. Varsha Singh (Professor), Department of Humanities & Social Science, Indian Institute of Technology Delhi	Member Secretary
16.	Dr. Ravi Krishnan Elangovan (Professor), Department of Biochemical Engineering & Biotechnology, Indian Institute of Technology Delhi	Alt. Member Secretary

The Chairperson of the Committee may co-opt an expert each from the fields of Animal House Expertise and Clinical Psychology.

Tenure: September 2025 to August 2026

Terms of reference:

- To look into the Ethical Consideration involved in Research on Human Subjects. As and when an experiment involving a student, member of faculty / employee of the Institute in a hazardous environment is identified and is to be initiated, it shall first be referred by the Deptt. / Centre / Programme concerned to the Safety Committee for advice / clearance. The Referral Committee will examine it and accord clearance or regret it.
- Any other matter referred to it by the Director.

Frequency of meetings: As and when required, a minimum of one meeting every six months.

Annual Report: The committee will submit its annual report by 30th June each year.

01/10/25

सहायक कुलसचिव (समन्वय)/Assistant Registrar(CDN)

Terms of Reference

1. To review and approve all research proposals involving human participants conducted at the Indian Institute of Technology Delhi.

2. To ensure that appropriate ethical and scientific standards are maintained to protect research participants from harm, including:
   (a) Assessing potential risks in relation to anticipated benefits, minimizing risks to the greatest extent possible, and ensuring that risks are reasonable in relation to the expected benefits, while considering not only the interests of current research participants but also broader societal interests and potential future beneficiaries; and
   (b) Basing decisions on submitted study documents, relevant supplementary information, and an informed understanding of the research context and stakeholder interests.

3. To grant approval with conditions, require remedial actions, re-submission or withdraw or suspend approval where ethical concerns arise or where studies fail to comply with approved protocols or ethical requirements.

4. To monitor the conduct of approved studies and to suspend or terminate a study when reasonable ethical concerns or risks to participants are identified.

5. To formulate, review, and recommend policies, procedures, and standards relating to the ethical conduct of research involving human participants at the Institute.

6. Research involving vulnerable populations shall be subject to full Committee review and enhanced ethical scrutiny, in accordance with applicable national ethical guidelines.

7. **Stem Cell Research:** Pursuant to the dissolution of the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and the Institutional Committee for Stem Cell Research (IC-SCR) on 3 March 2024, the Department of Health Research (DHR) authorized Institutional Ethics Committees to evaluate and approve stem cell research proposals. In accordance with this directive, the IEC-IITD is mandated to review and approve stem cell research proposals, with the requirement that at least two stem cell experts participate in the review process, of whom at least one shall be external to the host institution.

Membership requirement

A. Appointment letters shall be issued to each member by the Head of the Institution. These letters shall clearly outline the roles and responsibilities of the members, the duration of appointment, and the conditions governing membership, including expectations and obligations.

B. The initial term of appointment for IEC-IITD members shall be three (3) years. At the end of each three-year term, the Committee shall be reconstituted through a defined process, whereby one-third of the members shall be replaced. Members with the longest continuous tenure on the Committee shall be phased out first, and new members shall be appointed against the resulting vacancies. No member shall serve for more than two consecutive terms.

C. A member may be replaced during the term of appointment in the event of death, long-term non-availability, or if the member is deemed unfit to continue due to actions inconsistent with the responsibilities and ethical standards laid down in the applicable guidelines. Members may also resign from the Committee by submitting a written resignation with appropriate reasons to the competent authority.

D. All IEC-IITD members are required to maintain strict confidentiality regarding all Committee deliberations and documents and shall sign a confidentiality agreement at the time of appointment. Members must also declare any conflict of interest, if applicable, in relation to any proposal, discussion, or decision at any stage of the review process.

E. Honorarium and travel reimbursement, as applicable, shall be paid to external members of the IEC-IITD, and the applicable details shall be specified in the individual appointment letters.

Quorum

The following will constitute a quorum for IEC-IITD meetings:
1. Chairperson/Co-Chairperson (1)
2. Member-Secretary (1)
3. At least one of the following (1)
   -Basic Scientist/Social Scientist
   -Clinical Scientist
4. Legal Person (1)
5. Layperson or Social Scientist (1)

In total, a minimum of five (5) members must be present in the meeting room to constitute a quorum.

a) The quorum should include medical (preferably one pharmacologist) and non-medical/technical or non-technical members.
b) At least one non-affiliated member must be part of the quorum.
c) Preferably, the layperson should also be present during the meeting.
d) Decisions made during a meeting are valid only when the quorum is met.

Conduct of Meeting

A. The Chairperson conducts all meetings of the IEC-IITD. If for reasons beyond control, the Chairperson is not available; Vice-chairperson conducts the meeting.

B. The Member Secretary is responsible for organizing the meetings, maintaining the records, and communicating with all concerned. He/she prepares the minutes of the meetings and gets it approved by the Chairman before communicating to the researchers. If for reasons beyond control, the Member-Secretary is not available; co-convener conducts the meeting.

C. The records are archived for a period of 5 years from the end of the project.

D. e-archiving is being done in view of space and cost constraints. Where indicated, archiving may be done for a longer time.

E. The meetings can be held on virtual platform also.

IEC-IITD Office and Conduct Procedures

A. The IEC-IITD Office, under the supervision of the Member Secretary, shall receive all research proposals and maintain records of IEC activities, including submissions, reviews, decisions, and correspondence. Only complete applications shall be accepted for review, and incomplete applications shall be returned to the Principal Investigator within five working days along with checklist of required revision.

B. The Member Secretary shall conduct an initial screening of proposals to determine the appropriate category of review—full Committee review, expedited review, waiver, or exemption—in accordance with applicable ethical guidelines.

C. The Member Secretary shall coordinate the functioning of the IEC-IITD Office and schedule Committee meetings in consultation with the Chairperson and Committee members. Meetings shall ordinarily be held on a monthly basis.

D. When the number of proposals pending review exceeds five, an additional meeting may be convened in consultation with the Chairperson and subject to member availability.

E. Proposals eligible for expedited review, waiver, or exemption may be processed accordingly and, upon review by at least two IEC members and approval of the Chairperson, may be approved under the applicable category.

F. The Member Secretary shall prepare the minutes of all IEC-IITD meetings and submit them to the Chairperson for approval. Upon approval, the IEC-IITD Office shall communicate the Committee's decisions to the Principal Investigator in accordance with Institute procedures.

Independent consultants

IEC-IITD may call upon subject experts as independent consultants who may provide special reviews 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. They are required to give their specialized views but do not take part in the decision-making process which will be made by the members of the IEC-IITD. Member Secretary can take comments from experts (preferably prior to the meeting) if it is likely to assist the IEC-IITD in the review of the project.

Application Procedures

A. The IEC-IITD operates in accordance with this SOP, as published on the IIT Delhi Ethics website. Research proposals shall be submitted to the IEC-IITD under one of the following categories:
(a) fresh project submissions for approval (Full Committee / Expedited / Exemption);
(b) amendments to ongoing approved projects; and
(c) progress or closure reports of approved projects.

B. Applications shall be submitted using the prescribed forms available on the Ethics website and uploaded through the N-IRIS portal as a single consolidated PDF. The application must clearly indicate the category of review sought.

C. One printed copy of the complete application, duly signed by the Principal Investigator and Co-Investigators/Collaborators and forwarded by the Head of the Department, shall be submitted to the IEC-IITD Office.

D. Incomplete applications shall not be processed. Queries related to submission may be raised through the N-IRIS portal.

Selection Criteria for Members of the Institutional Ethics Committee (IEC-IITD)

Members of the Institutional Ethics Committee (IEC) at IIT Delhi shall be selected based on their qualifications, experience, interest, and commitment to the ethical review process. Willingness to dedicate time and effort to IEC responsibilities is a prerequisite. The following criteria must be met for appointment:

1. **Appointment Tenure & Replacement**
    - The initial appointment duration will be for 2-3 years.
    - Members may be replaced in the event of death, long-term unavailability, or actions deemed inconsistent with IEC responsibilities.

- Members may voluntarily resign by submitting a formal resignation with valid reasons.

2. **Commitment to Ethical Responsibilities**
   - Members must maintain absolute confidentiality regarding all discussions and deliberations during meetings.
   - Any conflict of interest must be declared at the beginning of each meeting.
   - Members must uphold the ethical review process and ensure the protection of research participants.
3. **Documentation & Training Requirements**
   - Submission of a recently signed CV.
   - Preferably, submission of training certificates in ethics and/or Good Clinical Practice (GCP). If unavailable at the time of induction, the member must submit these within six months of appointment.
   - Commitment to ongoing training and skill enhancement throughout tenure.
4. **Compliance with Ethical Guidelines**
   - Members must familiarize themselves with and adhere to relevant ethical guidelines and regulations.
   - They should be willing to disclose their full name, profession, and affiliation.
   - Acceptance of the committee's Conflict of Interest (COI) policy and declaration of any potential conflicts when necessary.
   - Signing of confidentiality and COI agreements is mandatory.
5. **Periodic Performance Review**
   - The SOP may include a mechanism for periodic review of IEC members' performance to ensure active participation and adherence to ethical principles.

By meeting these criteria, members contribute to maintaining the highest ethical standards in research at IIT Delhi.

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:

1. Functions of Chairperson (Non-affiliated)

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 represent 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 non-affiliated 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.

Qualifications - A well-respected person from any background with prior experience of having served/ serving in an EC.

2. Functions of Vice-Chairperson

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

3. Functions of the Member secretary (affiliated)

IEC-IITD member secretary will be responsible for execution of following activities:
Receive research proposals
Organize an effective and efficient tracking procedure for each proposal received
Prepare, maintain and distribute of study files
Review the proposals with two members and 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 to 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
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

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.

Qualifications - Should be a staff member of the institution, should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills

4. Function of Alternate Member Secretary

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

5. Basic medical scientist (Affiliated/ non-affiliated)

Review research proposals

Ensure continuing review process of Serious Adverse Events (SAE), protocol deviation progress and completion report.

Conduct benefit-risk assessment

For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

Qualifications - Should be individual/s with recognized medical qualification, expertise and training, in case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist

6. Function of Basic scientist (Affiliated/ non-affiliated)

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.

7. Function of Clinician (Affiliated/ non-affiliated)

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

Qualifications - Should be individual/s with recognized medical qualification, expertise and training

8. Function of Legal expert (Affiliated/ non-affiliated)

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.

Qualifications - Should have a basic degree in Law from a recognized university, with experience

9. Function of Social Scientist (Affiliated/ non-affiliated)
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. **Qualifications** - Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
10. Function of Lay person (non-affiliated)
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. **Qualifications -** Literate person from the public or community • Has not pursued a medical science/ health related career in the last 5 years • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities
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.

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 Requirements for Ethical Approval of Research Proposals

To ensure a thorough and efficient review, all research proposals must include the following documentation:

1. Investigator Information:

- **Principal Investigator (PI) and Collaborators:**
  - Provide the name, designation, and affiliation of the PI and all collaborators.
  - Note: IEC approval is granted only to permanent employees of the institute. Faculty/supervisors serve as PIs. IIT Delhi students may be listed as Co-PIs, trainees, or researchers.

2. Research Venue and Permissions:

- Specify the physical location(s) where the research will be conducted, and data will be collected.
- If the research occurs outside of IIT Delhi premises, provide a formal approval letter from the relevant institution or company granting permission.
- Apply on IRIS portal for the: Safe Research and attach a copy along with the application.

3. Institutional Approvals and Forwarding:

- All proposals must be forwarded by the Head of Department (HoD).
- Master's proposals must be forwarded by the program coordinator, Departmental Research Committee (DRC), and HoD.
- For Master's thesis proposals requesting exemption or expedited review, supervisors must include detailed project review reports and comments. Project evaluation committee comments, forwarded through the program coordinator, DRC, and HoD, will expedite the review process.

4. Research Protocol:

- Provide a comprehensive protocol outlining the scientific and ethical aspects of the research.
- Include a detailed research plan, methodology, sample details, materials, procedures, research design, and analysis plan.
- If available, include previously IEC-approved protocols as examples.
- The protocol should demonstrate that the research will produce sound scientific output using ethical methods.

5. Ethical Considerations:

- Clearly identify potential ethical issues and provide detailed plans to mitigate associated risks.
- This section should demonstrate a proactive approach to ethical considerations and facilitate open discussion with the IEC.

6. Proposal Components:

- Include all relevant supporting documents, such as case report forms, questionnaires, follow-up cards, and other pertinent materials.
- The proposal should be a concise document that is specifically for the IEC review. It should not be the same document that is used for SRC or project evaluation committee reviews.
- Include a brief background, methods, tools, materials, samples, procedures, analysis, and interventions.

7. Informed Consent:

- Provide the informed consent process, including Patient Information Sheets (PIS) written in vernacular language second person and informed consent forms should be written in first person in local languages.
- Adhere to ICMR 2017 guidelines, especially for vulnerable populations.
- Clearly state the format of informed consent (written or verbal) and storage procedures.
- If informed consent is not possible, provide justification and address the issue.

8. Drug/Device Trials:

- For drug/device trials, provide all relevant pre-clinical animal data and clinical trial data from other centers.
- Pilot data without IEC approval requires careful review. Piloting on human subjects should not occur before IEC approval, except in very rare cases of minimal risk, and even then, only on a very small number of participants.

9. Investigator Credentials:

- Provide CVs of all investigators, including relevant publications from the past five years.

10. Regulatory Clearances:

- Include details of any required regulatory clearances, especially for research involving international collaborations or biological sample transfers.
- For research that requires HSMC approval, the IEC can indicate eligibility.

11. Funding and Financial Disclosures:

- Disclose all funding sources and financial requirements for the project.
- This allows the IEC to assess project feasibility and potential conflicts of interest.
- Disclose any other financial issues, including insurance arrangements, especially for high-risk research.

12. Adverse Event Reporting:
- Provide a written agreement to report all Serious Adverse Events (SAEs).

13. Conflict of Interest:
- Provide a clear and specific statement of any potential conflicts of interest.

14. Compliance:
- Provide a statement of agreement to comply with all relevant national and international guidelines.

15. Participant Compensation and Insurance:
- Describe any compensation for study participation, indemnity arrangements for study-related injuries, and insurance coverage.

16. Previous Ethics Committees (ECs) Decisions:
- Disclose all significant previous decisions by other ECs or regulatory authorities, including reasons for negative decisions.

17. Publication Plans:
- Outline plans for publication of results (positive or negative), ensuring participant privacy and confidentiality.

18. Exemption/Expedited Review:
- For exemption and expedited reviews, include DRC chair approval, forwarded by the HoD.
- Master's thesis proposals must include documentation of research plan/proposal approval from supervisors, project committee evaluation, and the master's program coordinator.

19. Additional Information: Include any other information relevant to the study.

Research Involving Government Employees and Officials

Research involving interviews, surveys, or data collection from government employees or officials shall be conducted in accordance with applicable service conduct rules, institutional/organizational policies, public disclosure policy and ethical safeguards, so as to protect participants from professional, legal, or reputational risk.

A. Government employees or officials shall be informed and acknowledge that the views, opinions, or responses expressed are personal and do not represent the position of the Government, department, or institution, unless participation is in an officially authorized capacity (CIOMS-WHO, 2016).
B. Where participation requires prior approval from the employing government department or authority, government officials shall inform their superior/Competent authority and obtain written approval before participation, and the IEC-IITD may require documentary evidence of such approval during ethical review U.S. federal Common Rule (45 CFR 46), (ICMR Ethical Guidelines 2017, Section 9, Box 9.4).
   - Permission from organizational authorities shall not be construed as consent from individual employees, and refusal to participate shall have no bearing on the participant's employment or professional standing (ICMR Ethical Guidelines 2017, Section 5), (Nuremberg Code of 1947).
C. All information obtained from participants shall be stored, processed, and reported responsibly. Identifiable information shall not be disclosed without explicit permission. Data shall be used solely for academic purposes. Care shall be taken to avoid direct or indirect identification of participants in reports, presentations, or submissions, including through combinations of role,

designation, organization, or location.

D. Data obtained from government employees or officials shall be used solely for the stated research purpose and handled in accordance with applicable data protection, confidentiality, and ethical guidelines (ICMR Ethical Guidelines 2017, Section 3.3.2)
E. Audio or video recording of interviews shall be undertaken only with the explicit prior consent of the participant, and such consent shall be documented in the Informed Consent Form.
F. Projects involving sensitive topics, high-risk populations, reputational risk to institutions, or potential legal implications shall be referred to the IEC at the project planning stage or upon identification of such risks at any later stage, and in all cases at least four weeks prior to anticipated publication or dissemination.
G. Research involving government employees or officials shall be designed and conducted in compliance with applicable service conduct rules, including the *Central Civil Services (Conduct) Rules, 1964*, and relevant departmental instructions, to ensure that participation does not conflict with official duties or obligations (Haryana Civil Services (Government Employees' Conduct) Rules, 2016; Kerala Government Servants Conduct Rules, 1960, Amendment Rules, 2016; Gujarat Civil Services (Conduct) Rules, 1971; Karnataka Civil Service Conduct Rules, 1966

   Every Government employee shall, in the performance of duties and in good faith, communicate to a member of the public or any organization full and accurate information that is required to be disclosed under the Right to Information Act, 2005 (22 of 2005). Provided that, no Government employee shall, except in accordance with any general or special order of the Government or in the performance in good faith of assigned duties, communicate—directly or indirectly—any official document, part thereof, or any information to any person to whom they are not authorized to communicate such document or information.

   In accordance with applicable service conduct rules, including the All-India Services (Conduct) Rules, 1968, participants who are government employees shall not disclose, and researchers shall not solicit, any official document, part thereof, or information that the participant is not authorized to communicate in the course of their duties.

   Interviews shall not require or encourage participants, particularly government employees, to make statements amounting to adverse criticism of current or recent government policies, decisions, or actions in violation of applicable service conduct rules.

   Where academic discussion of policy issues is undertaken, care shall be taken to frame questions in an analytical and non-attributive manner, without seeking personal or official opinions that may place participants at professional or legal risk.

   Researchers shall not seek evidence, testimony, or statements from government employees in a manner that require prior sanction or authorization under applicable service conduct rules.

Checklist: Research Involving Government Employees and Officials

As a government employee/official, please complete the following checklist to ensure your participation complies with service conduct rules and institutional policies.

Requirement & Action Item	Yes	No	Justification / Remarks
I confirm that my participation is consistent with the **Central Civil Services (Conduct) Rules, 1964** (or my applicable service rules).	[ ]	[ ]	
My participation is manageable in the above-mentioned study alongside my official duties and professional obligations.	[ ]	[ ]	
I have coordinated with my competent authority regarding my participation in this study.	[ ]	[ ]	
I am willing to share the departmental approval/NOC with the **IEC-IITD** to support the ethical clearance of this project.	[ ]	[ ]	
I understand that my responses are provided in my personal capacity as a subject expert/official, and do not represent the position of my organization	[ ]	[ ]	
I understand that the study is designed to **anonymize** my identity (name, designation, and specific department) in all public dissemination.	[ ]	[ ]	
I am confident that data collected from me will be handled securely and used **solely** for the research purpose stated to me.	[ ]	[ ]	

16.Types of application

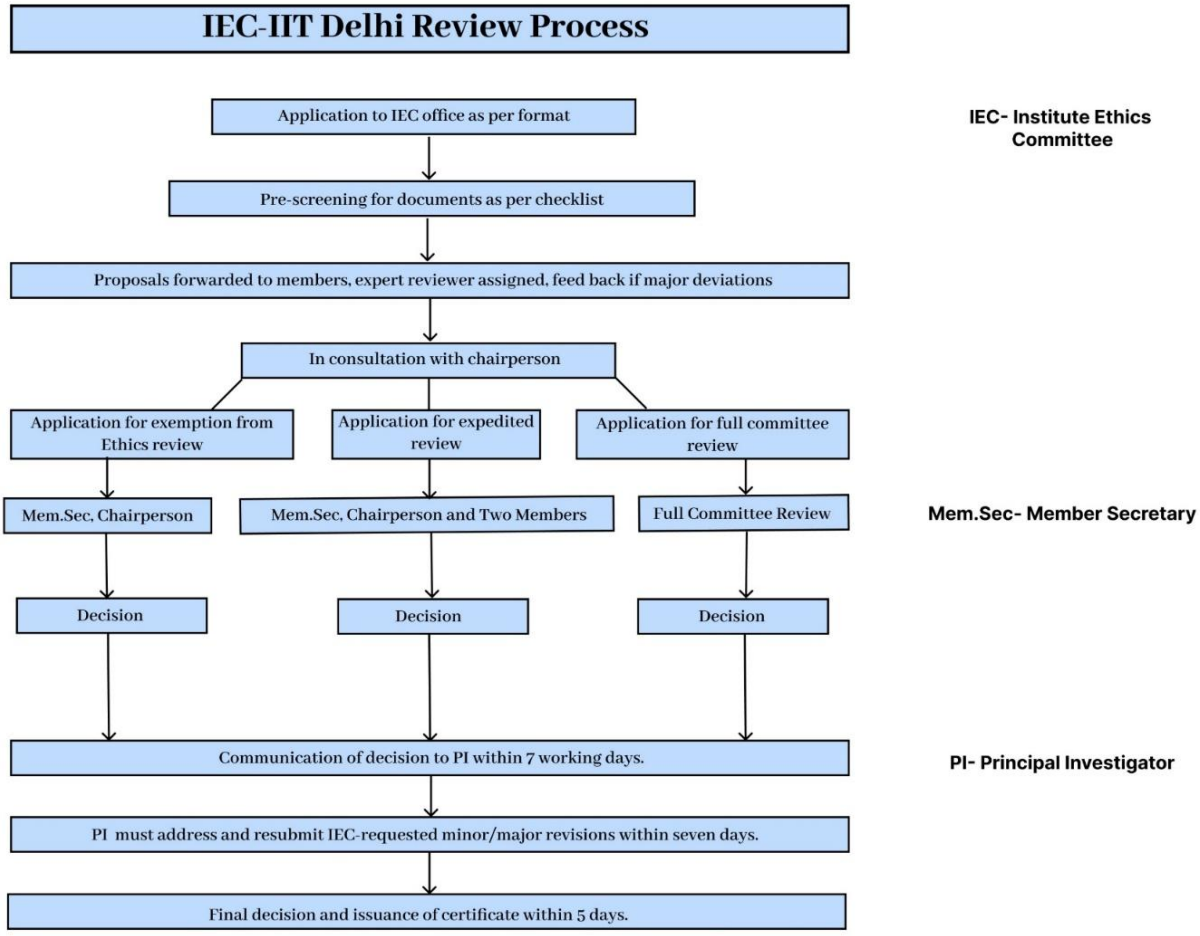
The Institute ethics committee will review the submissions/ proposals on the basis of the ICMR criterion and decide to review it in one of the following three types of communications. Please note that a full, complete proposal must be submitted for it to be reviewed and categorized in one of the three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

Note:

1. PI's will be required to be present for the IEC presentation.
2. Max 7-8 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).



Exemption from IEC-IITD Full Ethical Review

The ICMR guidelines (2017) provide criteria under which research protocols may be exempt from full ethical review. The IEC-IITD utilizes these guidelines to determine eligibility for exemption.

Eligibility Criteria for Exemption (Minimal Risk, No Linked Identifiers):

The Member Secretary/Alternate Member Secretary, in consultation with the Chairperson and one or two external members, will assess exemption eligibility based on the following:

1. **Research on Publicly Available Data:** Systematic reviews and meta-analyses using data from the public domain (see note on "Use of Data from Public Domain").
2. **Observational Studies of Public Behavior:** Observation and recording of public behavior without linked identifiers, where disclosure would not harm the observed individual.
3. **Institutional Quality Control/Assurance Audits.**
4. **Comparative Studies of Educational Techniques/Curricula:** Comparison of instructional techniques, curricula, or classroom management methods. (Note: Studies involving interviews or discussions with participants may require further review.)

5. **Consumer Acceptance Studies:** Studies related to taste and food quality.
6. **Government Public Health Program Evaluations:** Program evaluations by government agencies focused on refinement, improvement, or monitoring, without individual identifiers. (Note: Impact assessment projects and studies involving interviews with beneficiaries may require further review.)

Important Considerations:

- Researchers cannot self-determine exemption eligibility. All proposals must be submitted to the IEC for assessment.
- Researchers may request exemption, providing clear justification.
- The IEC retains the right to determine the appropriate review category (exempt, expedited, or full).

Exemption Determination Process

- The determination of an exemption from full ethical review involves a structured process to ensure consistent and responsible decision-making. If the submitted research protocol and related documents align with the established exemption criteria, the Member Secretary or Alternate Member Secretary, in consultation with the Chairperson and one or two external members, will conduct a review of the project's brief summary and the exemption request. Following this review, the Member Secretary will record the decision and communicate it to the Principal Investigator (PI).
- The IEC Secretariat will formally communicate the exemption decision to the PI within 30 days of the *complete* submission of the proposal. It is essential that all required documentation is submitted to trigger this timeframe. This ensures that the review process is initiated only when all necessary materials are available for a thorough assessment.
- Subsequently, the Member Secretary will inform the full IEC members of the exemption decision at the next scheduled full board meeting, and the decision will be recorded in the meeting minutes. Alternatively, the Member Secretary or Chairperson may choose to present the application for review and a decision regarding exemption at the next full board meeting.
- It is imperative that any proposed changes to the research protocol are submitted to the IEC for review and approval prior to implementation. All correspondence with the IEC office related to the exemption should include the Proposal Unique ID number for clear tracking.
- The IEC retains the authority to assess whether requested protocol changes alter the risk-benefit analysis of the study. If a change in the review or exemption category is deemed necessary, investigators will be required to resubmit the study protocol and related documents for a change review process.
- Research proposals granted an exemption from review will be subject to ratification by the full IEC committee. The full committee maintains the right to reverse or modify any decision made by a subcommittee or expedited review committee.
- Finally, upon completion of the study, investigators are required to submit completion reports to the IEC for record-keeping purposes.

Exemption for Public Health Program Research (ICMR, 2017)

- Public health activities, such as monitoring health status, risk factors, and service utilization, are essential for improving population health. These activities involve the systematic collection and analysis of data to inform disease prevention and control. While researchers may utilize this data to generate new insights for program enhancement and broader applications, ethical considerations remain paramount.
- Program evaluation, which employs scientific methods to assess program design, implementation, and effectiveness, may or may not involve direct interaction with human participants. This can include health personnel, patients, community members, and stakeholders, as well as the review of documents and observational data. Public health registries established by national authorities, using de-identified data, may be eligible for exemption from full ethical review.
- Specifically, public health program evaluations focused solely on program refinement and improvement, or those involving interviews with a large, geographically dispersed stakeholder population, *may* qualify for exemption. However, it is crucial to note that projects aiming for generalizable knowledge, ensuring scientific rigor, evaluating potential harm, or requiring public health authority approval necessitate full ethical review.
- **Regarding Impact Assessment Projects:** Whether a consulting project focused on impact assessment qualifies for exemption depends on its specific characteristics. If the project's primary aim is to improve an existing program, uses de-identified data, and poses minimal risk, it *may* be considered for exemption. However, most consulting projects that involve impact assessment involve interviews and interactions with beneficiaries and therefore will require full ethical review. If the project intends to generate generalizable knowledge, involves sensitive data, or carries potential risks, it will require full ethical review. The key is to distinguish between program improvement activities and research intended for broader scientific contribution.

Exemption/Expedited 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 truly 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 Twitter), or is it located within a closed or private group (e.g., 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 fewer 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 people's data unless they specify otherwise). Will you be asking questions of 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 a vulnerable population (see ICMR, 2017 guidelines), exemption and expedite review requests 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 offenses 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 the data. If there is a 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.

Ethical Review of Research Conducted as Part of Course Requirements

These guidelines are designed to assist supervisors and Principal Investigators (PIs) in determining the appropriate ethical review process for research involving human participants conducted as part of course, project, or dissertation requirements.

Master's Program Requirements: For research conducted as part of a Master's program requirement (e.g., coursework in research methods), requests for exemption must be accompanied by approvals from the program coordinator and the Departmental Research Committee (DRC).

Pedagogical vs. Research Objectives:

- Research conducted as part of a course credit requirement is generally assumed to be for pedagogical purposes, focusing on skill development (e.g., ethnographic interviewing, statistical analysis).
- The primary objective is skill acquisition, not the dissemination of research findings through scholarly publication.
- If the research is intended for publication, full ethical review is mandatory.
- Any research involving human participation necessitates ethical review, especially when the objective is to communicate research findings rather than solely develop research skills.
- Course instructors and supervisors are responsible for advising students on ethical approval requirements and initiating the process in a timely manner.

Exemption Criteria:

- Exemption eligibility must be determined in accordance with the ICMR 2017 guidelines.
- Generally, exemption may be considered for research involving observational data that is publicly available, unidentifiable, anonymized, and poses no risk, harm, or distress to participants.
- The research should not involve sensitive topics, vulnerable populations (as defined by ICMR), physiological measures, or interventions.

Master's Thesis Proposals:

- Master's thesis proposals must include documentation of research plan approval from the program coordinator and DRC approval forwarded by the Head of Department (HoD).
- The research should not involve clinical assessments or generate clinical data.
- Proposals must be submitted at the beginning of the semester in which the research outcome is due.
- Proposals that are part of a Master’s program requirement may be eligible for exemption/expedited review if they meet the criteria and have program coordinator and DRC approval.
- Program coordinator and DRC comments on potential risks will aid IEC deliberation.
- Regardless of exemption/expedited requests, proposals must include a study description, Patient/Participant Information Sheet (PIS), and a clear articulation of risks and benefits.

Vulnerable Populations and Ineligibility:

- Master's program research involving human participants is eligible for exemption/expedited review only if it does not involve vulnerable populations as defined by ICMR 2017.
- Vulnerable populations include those who are socially, economically, or politically disadvantaged; incapable of informed consent; have compromised autonomy; or are unduly influenced.
- Research involving vulnerable participants is not eligible for exemption or expedited review.

Process and Timelines:

- Supervisors must request exemption/expedited review before the research begins.
- If the research is exempted, informed consent, confidentiality, and anonymity must be maintained.
- If the research is not exempted, it will undergo expedited or full ethical review.
- Requests for exemption/expedited review should be made in time for students to complete their work.
- IEC meetings may be scheduled in March-April and December-January to facilitate thesis requirements.

Department Level Committees and IEC Members: A member of the IITD IEC may serve on a department-level committee, provided that conflicts of interest are avoided.

Expedited Review Process

Proposals posing minimal risk are eligible for expedited review. Revised proposals may also qualify, unless the main committee's full review is specifically required. Additionally, nationally relevant proposals requiring urgent review can be considered for expedited processing.

Mechanism for Expedited Review: To facilitate timely review, a subcommittee may be formed, consisting of the Member Secretary and a subset of scientific members, under the Deputy Chairperson. This subcommittee will review proposals and submit recommendations to the Chairperson for approval.

Eligibility for Master's Student Proposals: Principal Investigators (PIs) seeking expedited ethical approval for Master's student proposals must ensure the following conditions are met (refer to relevant sections for specific criteria).

Ineligibility: Research proposals involving vulnerable participants, as defined by the ICMR 2017 guidelines, are not eligible for exemption or expedited review.

Exemption/Expedited Decision Process:

- **Request for Additional Information:** The IEC office may request additional information from the PI. In certain cases, a meeting with the PI may be required for clarifications. The PI will be notified of the meeting date.
- **Engagement of Special Interest Groups:** The IEC-IITD may invite members of specific patient groups or other special interest groups (e.g., HIV, genetic disorders, social minority groups) to provide their perspectives. These individuals will attend as "Guests/Observers" and will be required to sign a confidentiality agreement and disclose any conflicts of interest. They will not have voting rights.
- **Communication of Decision and Revision Process:** The decision will be communicated in writing. If revisions are required, the revised document must be submitted within the specified timeframe or before the next meeting. The Member Secretaries, along with two committee members, will review the revised proposals and present them to the Chairperson for approval. The approximate approval time for proposals meeting the exemption or expedited review criteria is 14 days.

Risk Assessment: Determining the Appropriate Review Category

(Exempt, Expedite, Full review)

Assessing the level of risk involved in a research proposal is a complex undertaking that requires careful deliberation. While these guidelines provide general direction, the final determination rests with the Institutional Ethics Committee (IEC).

1. **Exemption (Low/Negligible Risk):**
    - Proposals that meet the specific criteria for waiver/exemption as outlined in the ICMR 2017 guidelines, signifying low or negligible risk, may be eligible for exemption.
    - These proposals typically involve minimal interaction with participants and pose no significant potential for harm.
2. **Expedited Review (Minimal Risk):**
    - Proposals involving minimal risk, but which present specific ethical challenges, may be considered for expedited review.
    - Examples of such challenges include, but are not limited to, maintaining anonymity or confidentiality, conducting thorough debriefing, managing participant payments, addressing complexities in obtaining informed consent, and navigating data sharing agreements with other institutions.
    - Expedited review is appropriate when the risk is low but requires specific attention to certain ethical aspects.
3. **Full Review (Considerable Risk):**
    - Proposals that do not meet the criteria for exemption or expedited review, and which involve considerable risk, will require full review by the IEC.
    - These proposals typically involve:
        - Interventions (e.g., medical, psychological, behavioral).
        - Vulnerable populations (as defined by the ICMR guidelines).
        - Collection of biological samples (e.g., blood, urine, tissue, cells, saliva).
        - Studies involving the assessment of physiological measures (e.g., pupillary response, respiration, heart rate, blood sugar, hormones, effects of drugs/medications).
        - Recording neural/physiological activity (e.g., EEG, ECG, eye tracking).
        - Brain imaging studies.
    - Principal Investigators (PIs) of these proposals will be required to present their protocols for full review.
    - In exceptional circumstances, such as when a protocol has already received approval from another IEC, the IEC may consider an expedited review, however this is not guaranteed, and the IEC has the final decision.

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 (Naval Mechanical Engineering Building), IIT Delhi. Internal telephone: +91-11-2659-1221.
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 other local language for the site of study)
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

Research involving vulnerable populations must be conducted with the utmost ethical sensitivity to safeguard against coercion, exploitation, and harm. The Institutional Ethics Committee (IEC) at IIT Delhi is committed to upholding the core ethical principles of respect for persons, beneficence, non-maleficence, justice, and fidelity in all such research. **Proposals involving vulnerable populations shall undergo comprehensive initial and continuing review exclusively by the full committee.** This procedural requirement serves as a critical safeguard, ensuring that all ethical dimensions are rigorously evaluated and responsibly addressed.

A **vulnerable individual** is one who is relatively or absolutely incapable of protecting their own interests due to **personal**, **contextual**, **hierarchical**, or **cognitive** limitations. These limitations may be:

- **Inherent** (e.g., mental illness, physical disability)
- **Situational** (e.g., poverty, disaster displacement)
- **Institutional or hierarchical** (e.g., students, subordinates)
- **Temporary or context-based** (e.g., illness, emotional distress)

Examples include:

- **Children** (under 18 years)
- **Women in special situations** (e.g., pregnant, lactating, culturally restricted)
- **Economically or educationally disadvantaged individuals**
- **Cognitively impaired or mentally ill persons**

- **Terminally ill patients**
- **People with stigmatizing/rare diseases**
- **Marginalized communities** (e.g., tribal groups, refugees)
- **Persons in dependent relationships** (e.g., employees, students, prisoners)
- **People in conflict zones or affected by disasters**

These individuals may be vulnerable due to:

- **Limited autonomy**
- **Lack of access to information or alternatives**
- **Dependency or fear of reprisal**
- **Coercion (direct or perceived)**

Ethical Principles for Involving Vulnerable Populations

All research involving such populations must demonstrate:

- **Voluntariness**: Participation must be free from coercion or undue influence.
- **Informed Consent**: Clear, understandable, and culturally appropriate consent procedures must be in place.
- **Respect for Dissent**: Ability to refuse or withdraw without fear of consequences.
- **Justified Inclusion**: Inclusion must be ethically and scientifically justified.
- **Risk Minimization**: All foreseeable harms must be mitigated.
- **Benefit Maximization**: Participants must derive direct or indirect benefit.
- **Privacy and Confidentiality**: Stringent data protection mechanisms must be in place.
- **Trust**: Relationships must be built on transparency and good faith.

Role of the IEC at IIT Delhi

1. Review Process

- Mandate **full committee review** for any protocol involving vulnerable participants.
- Ensure protocols are **not eligible for exemption or expedited review**, even if the research is non-medical.
- Conduct **enhanced scrutiny** of research design, consent procedures, community engagement, and risk-benefit balance.

2. Documentation Requirements

- Scientific and ethical **justification for including vulnerable populations**.
- **Risk minimization and benefit enhancement strategies**.
- Appropriateness of **language, literacy level, and cultural context** of consent materials.
- Mechanisms to **prevent and monitor coercion**, including undue inducement.

3. Consent and Assent Requirements

- Consent must be taken from a **Legally Authorized Representative (LAR)** when the participant lacks decision-making capacity.
- For **children aged 7–18**, both **assent** and **parental/guardian consent** are mandatory.
- An **impartial witness** must be present for all oral consent procedures or when participants are illiterate.
- **Continuous consent** should be emphasized — not a one-time event.

4. Community and Contextual Safeguards

- IEC may require **permission from community gatekeepers** (e.g., village heads, tribal councils) in case of collectivist or indigenous communities.
- Review plans for **benefit-sharing** and **post-study access to interventions**, especially for marginalized groups.
- IEC may conduct **site visits**, **ongoing reviews**, and request **interim reports** for high-risk studies.

Role of the Researcher

- **Justify inclusion** of vulnerable groups with appropriate scientific rationale.
- Clearly explain **inclusion/exclusion criteria** and avoid discrimination.
- Design **voluntary, non-coercive recruitment** and consent processes.
- Develop culturally appropriate **SOPs for consent**, including:
    - Use of local languages
    - Visual aids or verbal explanation
    - Simplified consent documents
- Take steps to **protect privacy**, ensure **confidentiality**, and address **stigmatization** risks.
- Allow participants to **dissent or withdraw at any stage**, without loss of benefits or fear of penalty.
- Provide appropriate **referral mechanisms** in case of emotional or psychological distress during participation.
- Maintain open communication with **caregivers, LARs, or community representatives**.
- Declare and manage any **conflicts of interest**.

Sponsors must:

- Provide **justification for research involving vulnerable groups** and ensure IEC oversight.
- Fund **insurance and compensation mechanisms** in case of harm.
- Support the research team in implementing **participant protection safeguards**.
- Facilitate **risk mitigation**, **monitoring mechanisms**, and **field-level safety**.
- Ensure researchers are trained in **ethics of vulnerability**.
- Comply with **national and international regulations** on participant protection and data safety.

Compensation for Research-Related Harm
In case of injury, illness, or harm arising from participation:

- Compensation must be provided in accordance with ICMR and applicable national laws.
- The protocol must specify the mechanism, responsible party, and timelines for compensation.
- Information about compensation rights must be part of the informed consent process.
- The IEC will assess the adequacy of the compensation plan during initial review.

Checklist for Researchers Involving Vulnerable Populations

Before submitting to the IEC, researchers must ensure:

- Clear justification for the inclusion of vulnerable groups.
- Defined benefits and risk minimization strategies.
- Protocol for informed consent/assent, including language and cultural considerations.
- Measures to prevent coercion or undue influence.
- Community approvals, if relevant.
- Compensation and insurance details.
- Confidentiality and privacy safeguards.
- Monitoring and complaint redressal mechanisms.
- Conflict of interest declaration.

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

Research involving vulnerable populations requires heightened ethical considerations due to the increased susceptibility of these groups to coercion, undue influence, or exploitation. Chapter VI of the ICMR guidelines provides a detailed framework for ethical research with these groups. *It defines vulnerable populations as those who, due to their social, economic, biological, or other circumstances, have limited capacity to protect their own interests. These may include, but are not limited to, children, persons with disabilities, individuals with mental illness or cognitive impairment, elderly individuals, economically disadvantaged populations, prisoners, indigenous populations, and pregnant women and fetuses.*

Personal disability: Physical or mental impairments.

- **Environmental burdens:** Circumstances like poverty, displacement, or conflict.
- **Social injustice:** Discrimination, marginalization.
- **Lack of power, understanding, or ability to communicate.**
- **Situations that prevent self-protection.**

Key principles in research involving vulnerable populations include:

- Equal right to benefit from research.
- Research must address the specific health needs of the group.
- Empowerment of participants to make informed decisions.
- Involvement of a Legally Acceptable Representative (LAR) when participants lack capacity to consent.
- Strict protection of privacy and confidentiality.
- Implementation of additional safeguards.

Examples of Vulnerable Populations:

- Economically and socially disadvantaged (unemployed, orphans, those below the poverty line, ethnic minorities, sexual minorities - LGBT).
- Unduly influenced individuals (by benefits or fear of retaliation).
- Children (up to 18 years).
- Women in special situations (pregnant, lactating, limited decision-making power).
- Tribal and marginalized communities.
- Refugees, migrants, homeless, those in conflict zones.
- Individuals with mental illness or cognitive impairment.
- Terminally ill patients.
- Those with stigmatizing or rare diseases.
- Individuals with diminished autonomy (students, employees, prisoners).

Role of Stakeholders:

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.

Key Point: As stated within the ICMR guidelines, and to re-iterate, it is imperative that: "Only the full committee should do accord approval and perform initial and continuing review of proposals involving vulnerable populations." This is a crucial procedural safeguard to ensure that all ethical implications are thoroughly considered.

Specific Vulnerable Groups and Considerations:

- **Children:**
  - Requires parental/LAR consent and child assent (if applicable).
  - Benefit-risk assessment is crucial.
  - Research must be in child-friendly settings.
- **Women in Special Situations:**
  - Respect for autonomy while considering cultural practices.
  - Special attention to pregnant or lactating women.
  - Strict confidentiality in sensitive research (e.g., domestic violence).
- **Sexual Minorities and Sex Workers:**
  - Privacy and confidentiality are paramount.
  - Representation from the community on the EC is recommended.
  - Community advisory boards are helpful.
- **Tribal Populations:**
  - Research must have direct benefits to the tribal population.
  - Approval from relevant authorities is required.
  - Informed consent in local language with community elders.
  - Benefit sharing is required for commercialization of tribal knowledge.
- **Individuals with Mental Illness or Cognitive Impairment:**
  - Careful assessment of capacity to consent.
  - Protection from coercion.
  - Addressing potential risks like suicidal ideation.
- **Individuals with Diminished Autonomy:**
  - Protection from coercion in hierarchical settings.
  - Ensuring freedom to decline or withdraw.
- **Terminally Ill Patients:**
  - Managing therapeutic misconception.
  - Careful benefit-risk assessment.
  - Post-trial access considerations.
- **Other Vulnerable Groups (Economically Disadvantaged, Homeless, Refugees):**
  - Justification for inclusion.
  - Protection from exploitation.
  - Careful consent processes.

These responsibilities are interconnected and grounded in the core ethical principles of the ICMR guidelines: respect for persons (autonomy, beneficence, non-maleficence), justice (fair distribution of risks and benefits), and fidelity (trustworthiness). By explicitly connecting the actions of researchers, ECs, and sponsors to these principles, we ensure that research involving vulnerable populations is conducted ethically and responsibly.

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.
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