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 will occur outside of IIT Delhi, 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) and informed consent forms 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.

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 a 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 of 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.