Title: Categorization of New Research Study Protocols Received for Initial Review

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[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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1. Purpose

The purpose of this SOP is to describe the procedure to categorize new research study protocols submitted by investigators for initial review into full board / expedited review or exemption from review process.

2. Scope

This SOP covers the process of categorization of new research study protocols submitted to Institutional Ethics Committee (IEC) for initial review. It does not cover subsequent submissions.

3. Responsibility

It is the responsibility of the Member-Secretary [in consultation with Chairperson (as applicable)] to categorise the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full board review, expedited review and exemption from review.

4. Detailed Instructions

4.1 New proposals received for initial review

- New research study proposals received by the 20th of the month will be considered for review in the next monthly meeting of the IEC. *(This date can be as per individual IEC's policy).*
- The Secretariat will ensure that application of the research proposal is complete in terms of required documents (if any essential document is not available, an explanation must be sought in writing for the IEC to review). (As per SOP 06/V1).

4.2 New proposals forwarded to Member Secretary

- The Secretariat will forward the soft copy of the research proposal to the Member Secretary for initial screening within 2 working days of receiving the proposal.

- The Member Sectretary will screen the research proposals and categorise the proposals as elaborated in Section 4.3 within 2 working days of receipt.

4.3 Categorisation of New proposals for review by IEC

The Member Sectretary [in consultation with Chairperson (as applicable)] will categorise the proposals into three types. The types of review processes and the criteria to decide the type of review are explained below (*www.icmr.nic.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, October 2006*):

- **Full Board Review:** When new research proposals and other related documents are tabled in a formally convened meeting of the Ethics Committee for detailed discussion and decision, this is called Full Board Review.
    - Research studies involving more than minimal risk to human study participants are required by national and international regulations to be reviewed by the Ethics Committee full board.
    - Research that is considered minimal risk but involves vulnerable populations may be referred for Full Board Review.
    - Research proposals that have undergone expedited review and are referred to Full Board as no decision could be reached.

- **Expedited Review :** When new research proposals and related documents undergo a speedy review process by only two or three designated (by the Chaiperson) Ethics Committee members this is called Expedited Review.
    - Expedited review may be sufficient if the research study involves not more than minimal risk as defined in the ICMR guidelines.
    - Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.
    - Research on interventions in emergency situations.

- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.
- Clinical studies of drugs and medical devices only when research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or
- Research on Disaster management.
- A PI may also apply to the IEC for expedited review if the proposed research study satisfies the criteria for expedited review as per ICMR Guidelines.

[The following are examples of documents that will undergo expedited review but are NOT in the category of INITIAL review

- *Revised proposal with minor modifications previously approved through full review by the IEC.*
- *Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.*
- *Other documents which would be considered for expedited review are as follows but may not restrict to:*
  - *Minor deviations from originally approved research during the period of approval (usually of one year duration)*
  - *Change in the name, address of sponsor*
  - *Change in contact details of principal investigator, and Member- Secretary, IEC*
  - *Request for change in principal investigator, co-investigator,*

change in any member involved in the research

- *Minor amendments in the protocol, case record form*

- *Minor corrections in budget*
- *Other administrative changes in the investigator brochure, informed consent document]*

- **Exemption from review:** When research fulfils the following criteria, the IEC may grant an exemption from review:
  - Research does not involve live human participants, is on data in the public domain or is on anonymised data derived from participants and the research has less than minimal risk to participants, an exemption from IEC review may be considered.
  - Examples that may be be eligible for exemption from review include:
    - Audits of educational practices
    - Research on microbes cultured in the laboratory
    - Research on immortalized cell lines
    - Research on cadavers or death certificates provided such research reveals no identifying personal data
    - Analysis of data freely available in public domain
  - A PI may also apply to IEC for exemption from review if he or she finds that the proposed research study satisfies the criteria for exemption.

5. Reference to other applicable SOPs:

- **SOP 06/V1**: *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP 7A/V1**: *Initial Full Board Review of New Research Study Protocols*
- **SOP 7B/V1**: *Expedited Review of New Research Study Protocols*
- **SOP 7C/V1**: *Exemption from the Ethics Review of Research Study Protocols*

6. **Glossary** (www.icmr.nic.in *Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, October 2006*)

- **Minimal Risk:** It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life. Example for minimal risk: A retrospective review of patient case records to determine the incidence of disease/ recurrence of disease]
- **Less than minimal risk:** Research, in which there is no known physical, emotional,psychological, or economical risk to the study participants. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.)

7. **Flow Chart**

No.	Activity	Responsibility
1	Receiving new research study proposal and related documents by a fixed date of the month	Secretariat
2	Verifying completeness of submitted research study documents	Secretariat
3	Forwarding of new proposals to Member-Secretary IEC	Secretariat
4	Categorization of the Protocols into 3 categories: full board, expedited review and exemption from review process	Member-Secretary/ Member Secretary in consultation with Chairperson (if applicable)