7.1. Purpose

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

7.2. 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.

7.3. Responsibility

It is the responsibility of the Member-Secretary [in consultation with Chairperson if necessary) 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.

7.4. Detailed Instructions

7.4.1New proposals received for initial review

- New research study proposals received on or before the date specified 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).

7. 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 Secretary will screen the research proposals and categorise the proposals as elaborated in Section 7.4.3 within 2 working days of receipt.

7.4.3 Categorisation of New proposals for review by IEC

The Member Secretary in consultation with Chairperson (if required) will categorise the proposals into three types of review processes, which along with the criteria to decide the type of review (www.icmr.nic.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, 2017) are explained below:

Full Committee 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 Committee Review.

- All research proposals presenting more than minimal risk that are not covered under exempt, emergency or expedited review should be subjected to full committee review, some examples are;
  - Research involving vulnerable populations, even if the risk is minimal;
  - Research with minor increase over minimal risk (see table 2.1 of ICMR guidelines 2017 for further details);
  - Studies involving deception of participants (see section 5.11of ICMR guidelines 2017 for further details);
  - Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
  - Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
  - Major deviations and violations in the protocol;

- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
- Research during emergencies and disasters either through an expedited review/scheduled or unscheduled full committee meetings. This may be decided by member secretary depending on the urgency and need;

  Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

- Expedited Review: When new research proposals and related documents undergo a speedy review process by only two or three designated (by the Chairperson) Ethics Committee members it 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.

For example;

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
- Research involving clinical documentation materials that are non-identifiable (data, documents, records);
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis.
- Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and

- For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local IEC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters covered by section 12 of ICMR guidelines 2017 [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.

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 eligible for exemption from review include:
  - Research conducted on data available in the public domain for systematic reviews or meta-analysis;
  - Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
  - Quality control and quality assurance audits in the institution;
  - Comparison of instructional techniques, curricula, or classroom management methods;
  - Consumer acceptance studies related to taste and food quality; and
  - Public health programmes by Government agencies such as programme evaluation where the sole purpose of the exercise is refinement and

improvement of the programme or monitoring (where there are no individual identifiers).

7.5 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

7.6. 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)