Title: Categorization of New Research Study Protocols for Initial Review

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SOP Constitution and Approval:

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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 before submission to full board / expedited review or exemption from review process to Institutional Human Ethics Committee (IHEC), MGMCRI.

2. Scope

This SOP covers the process of categorization of new research study protocols submitted to IHEC, MGMCRI for initial review. It does not cover subsequent submissions.

3. Responsibility

It is the responsibility of three Internal Members of IHEC [in consultation with Chairperson (as applicable)] to categorize the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full board review or expedited review or exemption from review.

4. Detailed Instructions

4.1 New proposals received for initial review

- New research study proposals received not less than 4 weeks prior to the subsequently scheduled IHEC meeting will be considered for categorization. Secretariat will ensure that the application of research proposal is complete in terms of required documents

4.2 New proposals forwarded to Member Secretary/Additional Member Secretary

- Secretariat will forward a copy of the research proposal to the Member Secretary/Additional Member Secretary for initial screening within 2 working days of receipt of the proposal.
- The Member Secretary/Additional Member Secretary shall forward the proposal to the Committee consisting of not less than 3 Internal Members to screen the research proposals and categorize them as elaborated in Section 4.3 within 5 working days of receipt.

4.3 *Categorization of new proposals for review by IHEC*

- The three Internal Members [in consultation with Chairperson (as applicable)] will categorize the proposals into any one of the three types as mentioned earlier. The processes of categorization 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, October2017):

- **4.3.1Full 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. The following types of proposals shall fall under the category for full board review.

    - Research studies involving more than minimal risk to human study participants as per national and international regulations.
    - Research that is considered minimal risk but involves vulnerable populations.
    - Research proposals that have undergone expedited review but could not be decided regarding.

- **4.3.2Expedited 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 this is called Expedited Review.

    - Proposals involving instructional techniques, curricula or class room management methods.
    - Proposals submitted after minor modifications of already approved proposals by full board of IHEC, Examples of minor modifications like -Change in the name, address of sponsor /PI, contact details of PI, Chairperson and or Member- Secretary of IHEC, Minor amendments in the protocol, case record form, Minor corrections in budget)
    - Request for change in principal investigator, co-investigator, change in any member involved in the research
    - Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
    - Other administrative changes in investigator brochure, informed consent document
    - Proposals involving clinical materials that have been collected for non-research or clinical purposes (i.e. patient care records and specimens).

- Proposals involving emergency outbreaks and disasters for can be approved to continue as pilot study when IHEC full review is not possible.
- Proposals **NOT** involving therapeutic, diagnostic, prophylactic and screening interventions.
- Proposals **NOT** involving vulnerable and special groups.
- Collection of data for research purposes through non-invasive procedures (not involving general anaesthesia 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 (studies that fall under the type 'Academic clinical trial' but not involving vulnerable population) except when studying drug interaction or conducting trial on vulnerable population or Research on Disaster management.

- **4.3.3Exemption from review:** When research fulfils the following criteria, the IHEC will grant an exemption from review:
  - Research that does not involve live human participants, as on data in the public domain or is on anonymised data derived from participants and the research has less than minimal risk to participants
  - Examples that may 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
  - PI may also apply to IHEC for exemption from review if he / she justifies that the research proposal falls under this category.

5. Reference to other applicable SOPs

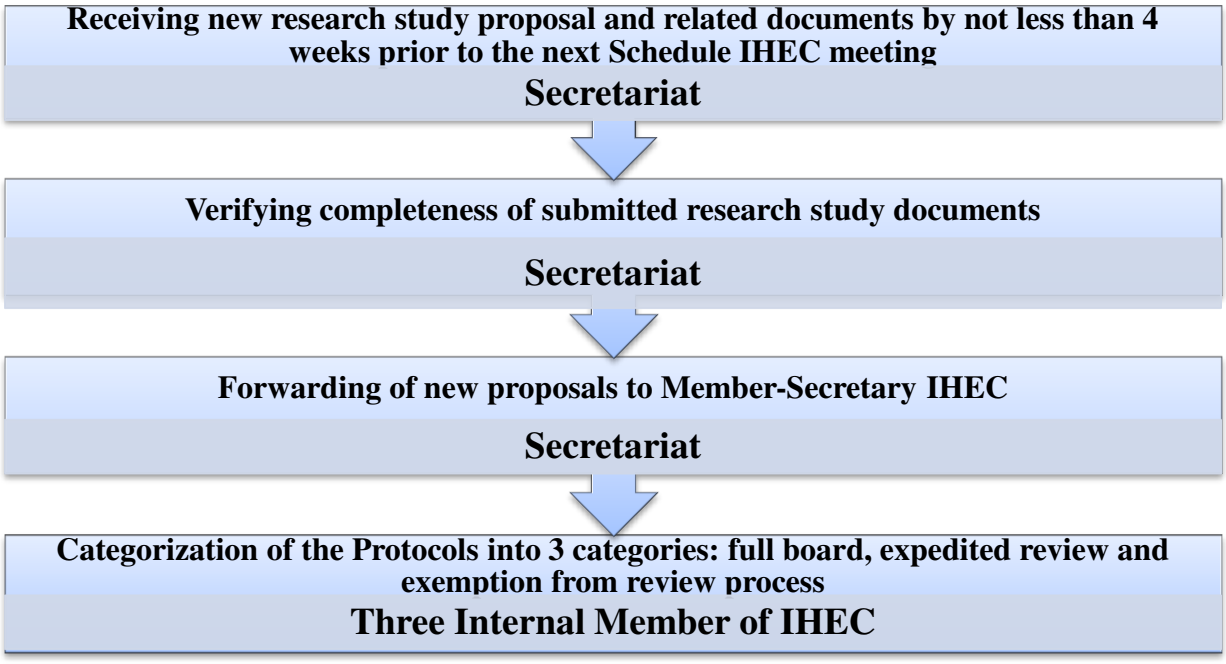
- **SOP 06/V2:**Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

- **SOP 7A/V2:** Full Board Review of New Research Study Protocols
- **SOP 7B/V2:** Expedited from the Ethics Review of Research Study Protocols

6. **Glossary** (www.icmr.in Ethical Guidelines for Biomedical Research on Human Participants, Indian Council of Medical Research, October 2017)

Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc

7. Flow Chart



8. References:

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*