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

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, to Sri Manakula Vinayagar Medical College and Hospital Ethics Committee (SMVMCH-EC).

2. Scope

This SOP covers the process of categorization of new research study protocols submitted to Sri Manakula Vinayagar Medical College and Hospital Ethics Committee 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 categorize the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: Full committee review, expedited review and exemption from review.

4. Detailed Instructions

4.1 New proposals received for initial review

- New research study proposals received from the Research Committee of Sri Manakula Vinayagar Medical College and Hospital will be considered for review in the next meeting of the EC.
- 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 EC to review).

4.2 New proposals forwarded to Member Secretary

- The Secretariat will forward the copy of the research proposal to the Member Secretary for initial screening within 5 working days of receiving the proposal.

- The Member Secretary will screen the research proposals and categorize the proposals as elaborated in Section 4.3 within 5 working days of receipt.

4.3 Categorization of New proposals for review by EC

The Member Secretary will categorize 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 National Ethical Guidelines for Biomedical and Health Research involving on Human Participants, Indian Council of Medical Research, and October 2017*):

Full committee review

All research proposals presenting more than minimal risk that are not covered under exempt 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 for further details);
- studies involving deception of participants (see section 5.11 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

Proposals that pose no more than minimal risk may undergo expedited review, 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 EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- research during emergencies and disasters (See Section 12 for further details).

Exemption from review

Proposals with less than minimal risk where there are no linked identifiers, for example;

- 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 Govt 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).

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

- **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.

5. Reference to other applicable SOPs:

- **SOP 06/V4**: *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP 7A/V4**: *Initial Full Board Review of New Research Study Protocols*
- **SOP 7B/V4**: *Expedited Review of New Research Study Protocols*
- **SOP 7C/V4**: *Exemption from the Ethics Review of Research Study Protocols*

6. Annexure; NIL

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 EC	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)

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017. (cited 23rd October 2018) available from: http: //www.icmr.nic.in.
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

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