Title: Categorization of protocols for review

SOP Code: SOP07/v4

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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date 7/6/23

Details of superseded SOP07

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP & NABH assessment

Details of current SOP07/v4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Glossary section added in the SOP 2. Categorization of risk specified as per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants - 2017 3. Harmonized terms referring to reviewers and discussants 4. Conflict of interest conditions strengthened

Table of Contents:

1. **Purpose:** The purpose of this SOP is to describe the procedure for categorizing protocols submitted to the YEC-1 for review into full review, expedited review or exemption from review, based on the recommendations of the ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) hereafter referred to as ICMR guidelines..

2. **Scope:** This SOP applies to the process of categorization of protocols submitted to the YEC-1 for review. These include:

   2.1. Initial protocol submissions

   2.2. Post Approval submissions:

      2.2.1. Amended protocols

      2.2.2. Periodic and continuing review of protocols

3. **Definitions:** The definitions of harm are as per ICMR guidelines

   3.1. **Risk:**

   3.2. **Less than minimal risk:** Probability of harm or discomfort anticipated in the research is nil or not expected. Examples:

      3.2.1. Research on anonymous or non-identified data/ samples,

      3.2.2. Data available in the public domain, meta-analysis, etc.

   3.3. **Minimal risk:** The 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

      3.3.1. Research involving routine questioning or history taking,

      3.3.2. Observing, physical examination, chest X-ray,

      3.3.3. Obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

   3.4. **Minor increase over minimal risk (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

      3.4.1. Research on children and adolescents;

      3.4.2. Research on persons incapable of giving consent;

      3.4.3. Delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials;

      3.4.4. 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.

      3.4.5. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

   3.5. **More than minimal risk (High risk):** Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include:

3.5.1. Research involving any interventional study using a drug, device or invasive procedures such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

4. Responsibilities:

4.1. The Chairperson will

4.1.1. Make note of all the decisions of categorization made by the Member-Secretary

4.1.2. Make note of and approve any change in categorization of the protocols submitted to the YEC-1 for initial review.

4.2. The Member-Secretary will:

4.2.1. Make an initial screening of the protocol and assess the possible risk to the participants as per the current national ethical guidelines.

4.2.2. Categorize the protocols into one of the three categories of initial review based on the assessment of the possible risk as per the ICMR guidelines

4.2.3. Fill the categorization form (Ann01/SOP07/v4) and marks the type of review processes for each protocol as

4.2.3.1. Full review

4.2.3.2. Expedited review

4.2.3.3. Exemption from review

4.2.4. Sign and date the categorization form

4.2.5. Assign the reviewers:

4.2.5.1. Primary reviewers (including legal expert and layperson - wherever applicable) and secondary reviewers (other members) for full review (SOP7A/v4)

4.2.5.2. Primary reviewers for expedited review (SOP7B/v4)

4.2.5.3. Primary reviewer for exemption from review (SOP7C/v4)

4.2.6. Consider change in categorization, if any reviewer wishes to do so

4.2.7. If Member-Secretary has a conflict of interest for the protocol, The Joint-Secretary/Chairperson/designated member of the EC will categorise the protocol

4.2.8. If several members of YEC-1 have a conflict of interest for a given protocol, then the Member-Secretary will request YEC-2 to take up the review process.

4.3. The Secretariat will

4.3.1. Inform the Member-Secretary when a complete protocol submission is received (within two calendar days) for the purpose of categorization.

4.3.2. Enter the type of categorization for each protocol in the database.

4.3.3. Change category of review process of the concerned protocol, whenever done so.

4.4. The YEC-1 Members will:

4.4.1. Return the complete protocol package, if they have a conflict of interest (within 2 calendar days of receiving the protocol for review), or are unable to review or attend the meeting for which the protocol is to be tabled

4.4.2. Suggest a change of category of review process, if required, during the protocol review process stating reasons for the same

4.4.3. Make this suggestion in the protocol assessment form, providing good justification for the change in review categorization type.

5. **Detailed instructions:**

5.1. **Submissions that require categorization:**

5.1.1. Protocols submitted for initial review

5.1.2. Amendment of protocols

5.1.3. Periodic or continuing review of protocols

5.2. **Forwarding of protocols:**

5.2.1. Secretariat will forward the documents to the Member-Secretary within 2 calendar days of receiving a complete protocol submission

5.2.2. The Secretariat will insert categorization and assessment form in the protocol file.

5.3. **Initial screening**

5.3.1. Member-Secretary will initially screen the protocol and the application form

5.3.2. Member-Secretary will assess the risk to participants as per the ICMR guidelines

5.4. **Categorization of the protocols:**

5.4.1. Member-Secretary will categorize the protocols into one of the three categories of initial review based on the assessment of the risk as per the ICMR guidelines.

5.5. **Re-categorization of the protocols:**

5.5.1. Since the initial categorization of protocols by the Member-Secretary is based on initial screening of the protocol and the application form, the primary reviewers/ reviewers may reassess the risk during the detailed review of the protocol and request change in the categorization of the protocol, if a discrepancy exists

5.5.2. The members will make this suggestion in the protocol review assessment form, providing justification for the change in review categorization type.

5.5.3. The Member-Secretary will consider the change in categorization

5.5.4. In case of any disagreement with the suggestion of the primary reviewer/reviewer, the Member-Secretary will consult the Chairperson for a decision

5.5.5. Member-Secretary will inform Chairpersonof any decision on recategorization

5.6. **Criteria to be followed for categorization of protocols received for initial review:**

5.6.1. ICMR guidelines are followed

5.6.2. This will be based on assessment of risk, as provided in Definitions above.

5.7. **Criteria for Full review categorization:**

5.7.1. Research protocols presenting more than minimal risk

5.7.2. Research with minor increase over minimal risk, if vulnerable population involved.

5.7.3. Research involving deception of participants

5.8. **Criteria for expedited review:**

5.8.1. Research that poses no more than minimal risk

5.8.2. Research with minor increase over minimal risk provided the research does not involve vulnerable populations

5.8.3. Research involving delinked specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples

5.8.4. Research involving clinical documentation materials that are de-linked (data, documents, records, radiographs, lab-reports) and pose no more than minimal risk;

5.8.5. Research during emergencies and disasters

5.8.6. The protocols involving vulnerable populations, may be categorized as expedited review only if the risk is 'less than minimal or minimal'

5.9. **Criteria for exemption of protocols from review: Proposals with less than minimal risk where there are no linked identifiers, and are of the following category:**

5.9.1. Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;

5.9.2. Quality control and quality assurance audits in the institution; comparison of instructional techniques, curricula, or classroom management methods;

5.9.3. Consumer acceptance studies related to taste and food quality;

5.9.4. 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).

5.9.5. Research not involving human participants

5.9.6. Research on educational practices (provided data are anonymized)

5.9.7. Research on microbes cultured in the laboratory (anonymized and de-linked)

5.9.8. Research on cell lines (provided data are anonymized and de-linked)

5.9.9. Research on cadavers or death certificates (anonymized and delinked)

5.10. **Further management of protocols:**

5.10.1. SOP7A/v4 for Full review

5.10.2. SOP7B/v4 for Expedited review

5.10.3. SOP7C/v4 for Exemption from Review

5.10.4. SOP9B/v4 for Amendment of protocols

5.10.5. SOP10/v4 for Periodic and continuing review of protocols

6. References:

6.1. SOP7A/v4: Full review of protocols

6.2. SOP7B/v4: Expedited review of protocols

6.3. SOP7C/v4: Exemption from review

6.4. ICMR National Ethical Guidelines for biomedical and healthcare research involving human participants, 2017

7. Annexures:

7.1. Ann01/SOP07/v4: Form for Categorization of protocols and assignment of leads discussants/primary/secondary reviewers

Ann01/SOP07/v4:
Form for Categorization of protocols and assignment of reviewers

Part A: Categorization of protocols		
1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-Investigators (All names)	
5	Department:	
6	Date of receipt of protocol	
Type of study:		
Initial risk assessment: 1. Less than minimal risk 2. Minimal risk 3. Minor increase over minimal risk or Low risk: 4. More than minimal risk or high risk Vulnerable population involved: Yes/No		
Categorization of the protocol: 1. Full review 2. Expedited review 3. Full review		
Signature of the Member Secretary with date:		
Signature & date of Joint Secretary/ Chairperson in case Member Secretary has CoI:		

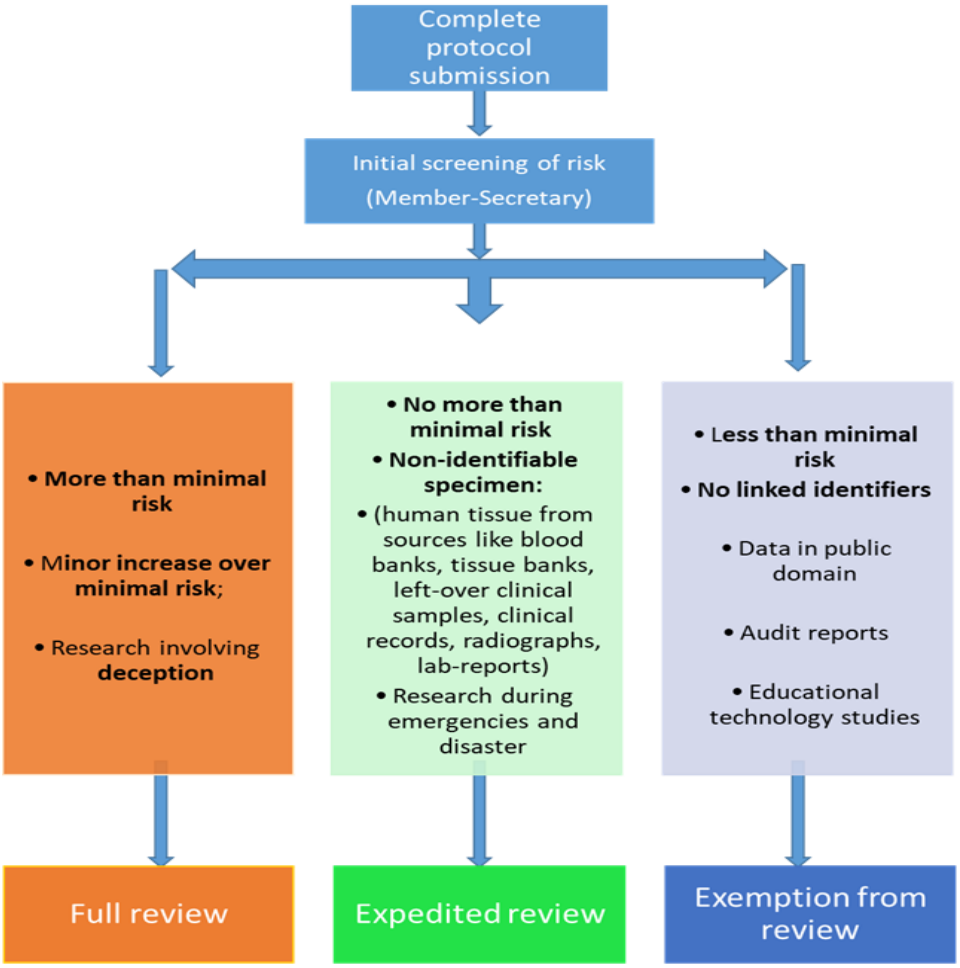
Part B: Assignment of primary reviewers/reviewers**:**

Action	**Details**	**Date identified**	**Date communicated**
Primary reviewers (For full review protocols)			
Reviewers assigned (For all protocols)			
Independent consultant (If required)			

Signature of the Member Secretary with date:

Signature of Joint Secretary/ Chairperson in case the Member Secretary has a conflict of interest with date:

8. Flowchart



9. Glossary:

AE: Adverse event

ICMR: Indian Council of Medical Research

Primary reviewer: The EC member who is assigned review of the full review protocol and takes the lead in discussing the protocol during the YEC-1 meeting. In the case of expedited review, the EC member who is assigned review of an expedited review protocol

Secondary reviewer: The EC members other than the primary reviewers, in the case of full review