Title: Categorization of protocols for review

SOP Code: SOP07/v3

Effective date: 03/10/2019

Prepared by:

Dr. Uma Kulkarni Member, YEC-1 SOP Subcommittee	Signature with date 3/10/2019

Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date 30 OCT 19

Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date 3/10/19

Notified by:

Registrar, Yenepoya deemed to be University	Signature with date 3/10

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.

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

2.1. 2.1 Initial protocol submissions

2.2. 2.2 Post Approval submissions:

2.2.1. 2.2.1 Amended protocols

2.2.2. 2.2.2 Periodic and continuing review of protocols

3. Definitions:

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

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

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

3.2. 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

3.2.1. Research involving routine questioning or history taking,

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

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

3.3. 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

3.3.1. Research on children and adolescents;

3.3.2. Research on persons incapable of giving consent;

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

3.3.4. 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. Such research should have a social value.

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

3.4. 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:

3.4.1. 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 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 (National Ethical Guidelines for Medical and health care research involving human participants - 2017)

4.2.3. Fill the categorization form (Ann01/SOP07/v3)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 based on the categorization of protocols as per SOP7A/v3 for full review, SOP7B/v3 for expedited review and SOP7C for exemption from review in the

4.2.6. Communicate the decision to the secretariat to initiate the review process further course of action

4.2.7. Consider change in categorization, if one or both the reviewers wishes to do so

4.3. The Secretariat will

4.3.1. Inform the Member-Secretary when a complete protocol submission is received within two calendar days of receipt.

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

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

4.4. The YEC-1 Members will:

4.4.1. Suggest a change of category of review process, if required, during the review process stating reasons for the same, even if it has been otherwise assigned by the Member-Secretary

4.4.2. 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. The Secretariat will forward the documents to the Member-Secretary within 2 calendar days of receiving it in the YEC-1

5.2.2. The Secretariat will insert the categorization and review assignment form in each protocol file.

5.3. Initial screening

5.3.1. The Member - Secretary will do an initial screening of the protocol and the application form

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

5.4. Categorization of the protocols:

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

5.4.2. The secretariat forwards the complete protocol document to the member secretary within 2 calendar days of receiving it in the YEC-1

5.5. Re-categorization of the protocols:

5.5.1. Since the initial categorization of protocols is based on the initial screening of the protocol and the application form, the reviewers may feel the need to change the categorization of the protocol during the detailed review of the protocol

5.5.2. The reviewer has the option to suggest a change of category of review process, based on a detailed risk: benefit assessment, even if it has been otherwise categorized

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

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

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

5.5.6. The member-Secretary will inform the Chairperson of any decision on recategorization of protocols.

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

5.6.1. The National Ethical Guidelines for Biomedical research on human participants published by the Indian Council of Medical Research for categorization are followed

5.6.2. This will be based on assessment of risk, a brief description of which is provided below in the section 'Glossary'.

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**;

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 involving **non-identifiable** specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples

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

5.8.4. Research during emergencies and disasters

5.8.5. The protocols involving vulnerable populations, may be categorized as expedited review only if the risk is 'less than minimal' and reviewed as per SOP7B/v3.

5.9. Criteria for exemption of protocols from review:

5.9.1. Proposals with **less than minimal risk** where there are **no linked identifiers**, and are of the following category:

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

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

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

5.9.1.4. 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).

5.9.1.5. Research not involving human participants

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

5.9.1.7. Research on microbes cultured in the laboratory (provided data are anonymized and de-linked from any possible identifiers)

5.9.1.8. Research on cell lines (provided data are anonymized and de-linked from any possible identifiers)

5.9.1.9. Research on cadavers or death certificates (anonymized) which do not bear any identifying personal data

5.10. Further management of protocols:

5.10.1. The protocols are further managed as per the SOPs for various categories of review

5.10.1.1. SOP7A/v3 for Full review

5.10.1.2. SOP7B/v3 for Expedited review

5.10.1.3. SOP7C/v3 for Exemption from Review

5.10.1.4. SOP9B/v3 for Amendment of protocols

5.10.1.5. SOP10/v3 for Periodic and continuing review of protocols

6. Reference to other SOPS:

6.1. SOP7A/v3: Full review of protocols

6.2. SOP7B/v3: Expedited review of protocols

6.3. SOP7C/v3: Exemption from review

7. Annexures:

7.1. Ann01/SOP07/v3: Form for Categorization of protocols and assignment of reviewers

Ann01/SOP07/v3:

Form for Categorization of protocols and assignment of reviewers

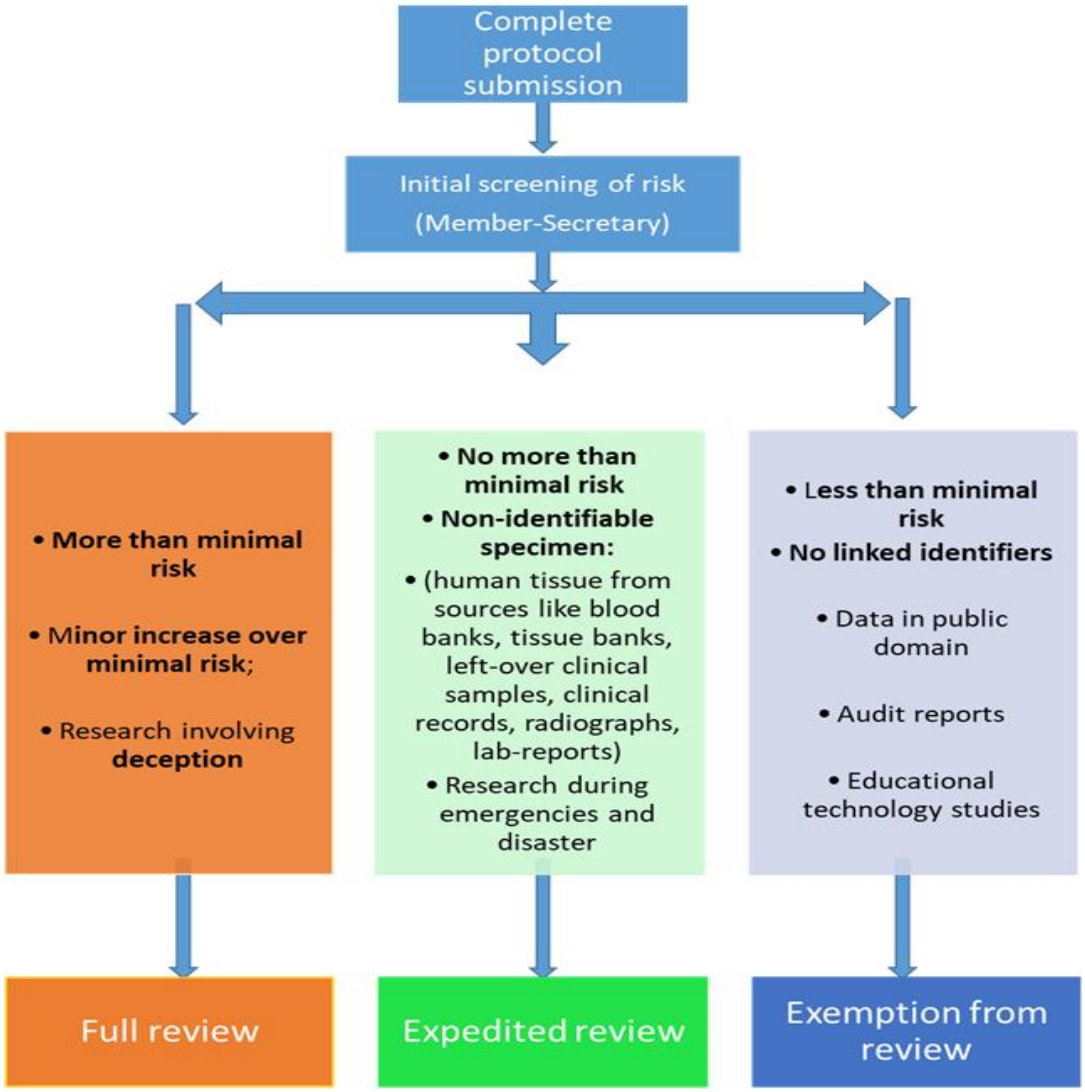
Part A: Categorization of protocols
Protocol Number Title of the protocol: Name of the PI: Department:
Initial risk assessment: 1. Less than minimal risk 2. Minimal risk 3. Minor increase over minimal risk or Low risk: 4. More than minimal risk or high risk
Categorization of the protocol: 1. Exemption review 2. Expedited review 3. Full review
Signature of the Member Secretary with date:

Part B: Assignment of reviewers:

Action	**Details**	**Date identified**	**Date communicated**
Reviewers assigned	1. . 2. . 3. . 4. . 5. .		
Independent consultant	1.		

Signature of the Member Secretary with date:

8. Flowchart


Complete protocol submission
Initial screening of risk (Member-Secretary)
• More than minimal risk
• Minor increase over minimal risk;
• Research involving deception
• No more than minimal risk
• Non-identifiable specimen:
• (human tissue from sources like blood banks, tissue banks, left-over clinical samples, clinical records, radiographs, lab-reports)
• Research during emergencies and disaster
• Less than minimal risk
• No linked identifiers
• Data in public domain
• Audit reports
• Educational technology studies
Full review
Expedited review
Exemption from review