Title: Categorization of new research protocols for initial review

SOP Code: YEC2/SOP07/v2

Prepared by:

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Approved by:

Dr. Prasanna Keshava B Chairperson , YEC2	Signature with Date 25/02/2023

Notified by:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date 14/03/23 Registrar YENEPOYA (Deemed to be University)

Details of superseded SOP 07/v1

Subcommittee Convenor name	Version no	Effective date (dd/mm/yy)	Describe the main changes
Dr.Prabhakar Adake	v1	14.06.2018	Major revision in the SOP

Details of Current SOP 07/v2

SOP subcommittee convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. Rashmi Jain	V2	25.02.2023	Major revision in the SOP

Table of Contents:

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for drafting, reviewing, distributing and amending SOPs of Yenepoya Ethics Committee 2 (YEC 2). The SOPs provide clear, unambiguous instructions so that all the activities of the committee are conducted in an orderly, fair and transparent manner, in accordance with Indian regulations and relevant, national and international ethical guidelines.

2. Scope

This SOP covers the procedures of drafting, reviewing, distributing and amending the SOPs of YEC 2.

- Initial protocol submissions
- Post Approval submissions:
- Amended protocols
- 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. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc

3.2.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.

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 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.

3.4.More than minimal risk or High 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.

3.5. 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.

(As per ICMR guidelines)

4. Responsibilities

4.1. Role of the Chairperson, YEC 2

It is the responsibility of the Chairperson, YEC 2 to

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 YEC2 for initial review.

5. The Member-Secretary will:

5.1.1. It is the responsibility of the Member-Secretary to categorize the new research protocols submitted to the YEC 2 for initial review. This is based on an initial screening of the protocol. The categorization will be done based on the possible risk to the research participants into any of the three types of review processes·

- Full review
- Expedited review
- Exemption from review.

5.1.2. In the case of a protocol expected to be kept for "full review", the Member-Secretary will make the decision and communicate the same to the Secretariat for further action.

5.1.3. During the review process, the reviewer considers a change in the review process of a given protocol, and then it is the responsibility of the Member-Secretary to consider the change of review category and make the final decision of categorization of protocols. The final decision rests with the Member-Secretary. Once a review process is identified and the initial review completed, the review process will not be changed.

5.1.4. Sign and date the categorization form

5.1.5. Assign the reviewers based on the categorization of protocols as per SOP7A/v2 for full review, SOP7B/v2for expedited review and SOP7C for exemption from review in the

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

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

6. Role of the Secretariat, YEC 2

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

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

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

7. The YEC2 Members will:

7.1.1. 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

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

8. Detailed instructions:

8.1. Submissions that require categorization:

8.1.1. Protocols submitted for initial review

8.1.2. Amendment of protocols

8.1.3. Periodic or continuing review of protocols

8.2. Forwarding of protocols:

8.2.1. The Secretariat will forward the documents to the Member-Secretary within 2 calendar days of receiving it in the YEC2.

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

8.3. Initial screening

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

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

8.4. Categorization of the protocols:

8.4.1. 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.

8.4.2. The secretariat forwards the complete protocol document to the member secretary within 2 calendar days of receiving it in the YEC2.

8.5. Re-categorization of the protocols:

8.5.1. 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

8.5.2. 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

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

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

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

8.5.6. The member-Secretary will inform the Chairperson of any decision on re categorization of protocols

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

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

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

8.7. Criteria for Full review categorization:

8.7.1 Research protocols presenting more than minimal risk

8.7.2. Research with minor increase over minimal risk;

8.7.3. Research involving deception of participants

8.8. Criteria for expedited review:

8.8.1. Research that poses no more than minimal risk

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

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

8.8.4. Research during emergencies and disasters

8.8.5. The protocols involving vulnerable populations, may be categorized as expedited review only if the risk is 'less than minimal' and reviewed as per SOP7B/v2.

8.9. 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:

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

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

8.9.3. Consumer acceptance studies related to taste and food quality

8.9.4. 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).

8.9.5. Research not involving human participants

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

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

8.9.8. Research on cell lines (provided data are anonymized and delinked from any possible identifiers)

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

8.9.10. Further management of protocols:

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

8.10.1.1. SOP7A/V2 for Full review

8.10.1.2. SOP7B/V2 for Expedited review

8.10.1.3. SOP7C/V2 for Exemption from Review

8.10.1.4. SOP9B/V2 for Amendment of protocols

8.10.1.5. SOP10/V2 for Periodic and continuing review of protocols

9. Reference to other SOPS:

9.1. SOP7A/V2: Full review of protocols

9.2. SOP7B/V2: Expedited review of protocols

9.3. SOP7C/V2: Exemption from review

10. Annexures:

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

Ann01/SOP07/v2:

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: 11. Less than minimal risk 12. Minimal risk 13. Minor increase over minimal risk or Low risk: 14. More than minimal risk or high risk

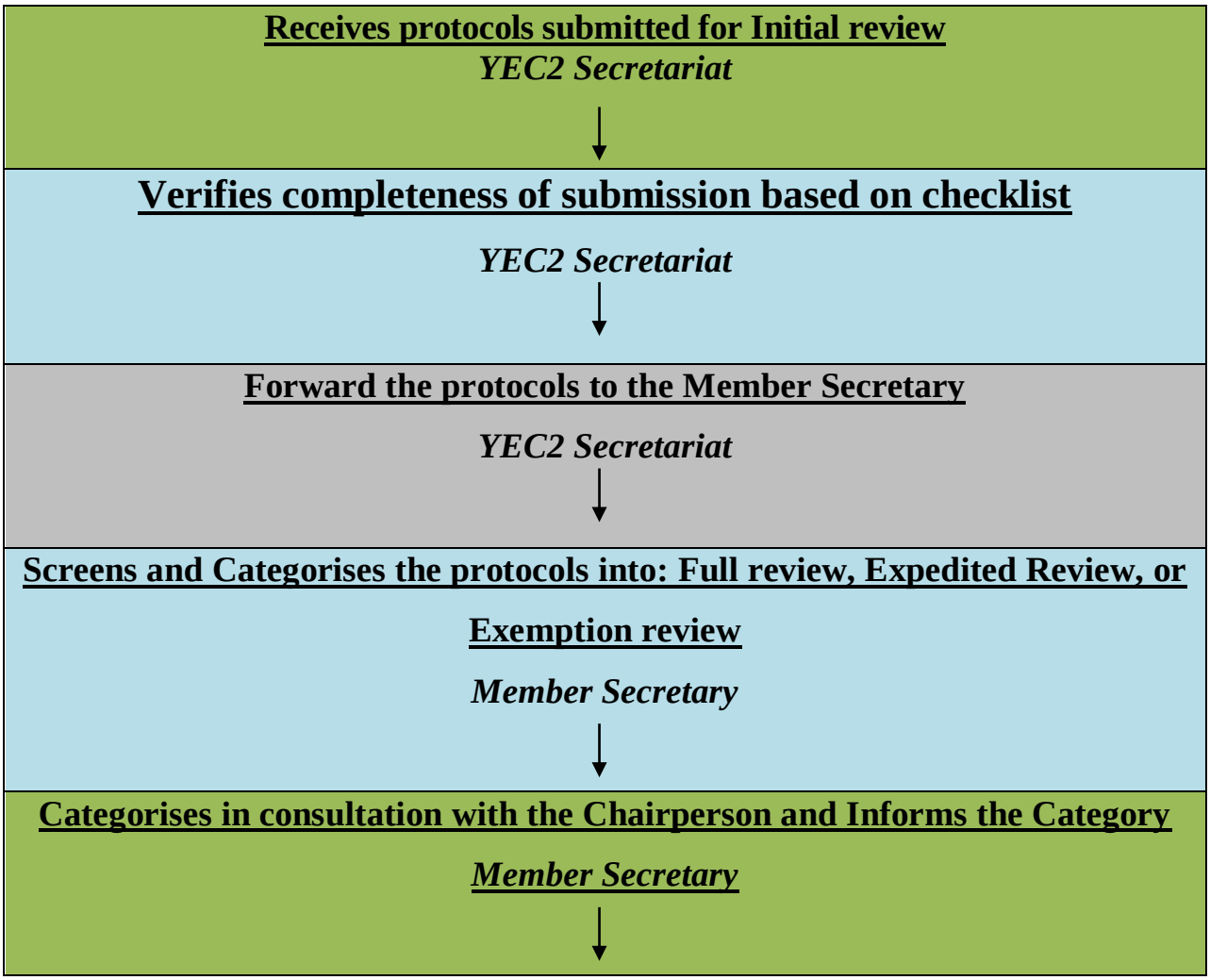
Categorization of the protocol: 1. Exemption review 2. Expedited review 3. Full review
Signature of the Member Secretary with date:

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:

11 Flow Chart



7. References

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6 th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf