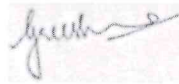


**Title: Review of Resubmission of protocol and related documents**


**SOP Code: SOP9A/v1**

**Effective Date: 01/1/2025**

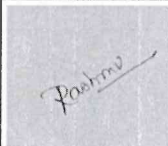
**Prepared by:**

Dr. Greeshma. B. Kotian YEC-4 SOP Subcommittee	 22.12.2024 Signature with date
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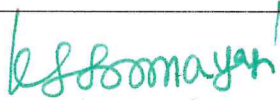

**Reviewed by:**

Mrs. Liba Sara Varghese Member, YEC-4 SOP Subcommittee	 22.12.2024 Signature with date
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**Approved by:**

Dr. Rashmi K S, Chairperson, YEC-4	 22.12.2024 Signature with Date
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**Notified by:**

Registrar, Yenepoya (deemed to be University)	 22/12/24  Signature with date:
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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe how the YEC-4 manages the review of resubmitted protocol
2. **Scope:** This SOP applies to the review of protocols and related documents that are resubmitted to the YEC-4 by the Principal Investigator (PI) in response to clarifications and modifications sought by the YEC-4 in the initial review.
3. **Responsibility:**

**3.1. YEC-4 Chairperson will:**

- 3.1.1. Ensure that the resubmissions are reviewed in a timely manner

**3.2. YEC-4 Member-Secretary will:**

- 3.2.1. Categorize the resubmissions as per the decision of the initial review
- 3.2.2. Assign the reviewers as per the decision of the initial review
- 3.2.3. Include all “resubmissions for full review” in the agenda of the subsequent YEC-4 meetings

**3.3. YEC-4 Secretariat will:**

- 3.3.1. Check the completeness of the resubmitted documents
- 3.3.2. Send the relevant documents to the initial reviewers (or Member-Secretary)

**3.4. YEC-4 Members will:**

- 3.4.1. Review the resubmissions when assigned, fill the assessment form, and provide the provisional decision as per the form

**4. Definitions**

- 4.1. Resubmission:** Resubmission of protocol refers to the protocol and/or the protocol related documents which are submitted to YEC-4 in response to clarification sought by the YEC-4 or to the recommendation made by YEC-4 following the review of

- 4.1.1. Initial review
- 4.1.2. Review of resubmission

- 4.2. Resubmission for expedited review:** Any resubmission which is categorized for expedited review after

- 4.2.1. Initial full review (Decided in the meeting and recorded in the decision form)
- 4.2.2. Initial expedited review

- 4.3. Resubmission for full review:** Any resubmission categorized for full review after

- 4.3.1. Initial full review (Decided in the meeting and recorded in the decision form)
- 4.3.2. Initial expedited review where reviewer requests discussion in the meeting.

## 5. Detailed instructions

### 5.1. Instructions to PI for resubmissions: All resubmitted documents should have

- 5.1.1. Protocol or related documents with changes incorporated (hard and soft copy)
- 5.1.2. Updated version number for each resubmitted document
- 5.1.3. Page numbers
- 5.1.4. Date of resubmission
- 5.1.5. All changes highlighted
- 5.1.6. Signatures wherever required

### 5.2. The resubmission application form: The PI must enter the following details

- 5.2.1. YEC-4 queries/recommendations (Ann01/SOP9A/v1)
- 5.2.2. The detailed response of the PI to the query (Ann01/SOP9A/v1)
- 5.2.3. The page number in the document where the change is made
- 5.2.4. In case the PI has not made/is unable to make the change recommended by the YEC-4, then an explanation/justification for the same
- 5.2.5. Each query / recommendation must be responded to separately
- 5.2.6. The form must be signed and dated by the PI and guide (wherever applicable)

### 5.3. Timelines for resubmission:

- 5.3.1. All resubmissions must be done at least 7 calendar days before a YEC-4 meeting if it is considered for a full review.
- 5.3.2. Any resubmission which is received later, will be considered for the subsequent YEC-4 meeting.
- 5.3.3. All resubmissions must be done within 180 calendar days of the last YEC-4 communication, failing which, the file will be considered as closed.
- 5.3.4. The review time for resubmission must be completed within 7 calendar days

### 5.4. Receipt of the resubmission:

- 5.4.1. Secretariat will check resubmission form completeness
- 5.4.2. The Secretariat will check whether version number, page number and highlighting is done in the resubmitted documents
- 5.4.3. The Secretariat will verify whether the date of resubmission falls within 180 calendar days from the date of the last YEC-4 communication

### 5.5. Review of the resubmission:

- 5.5.1. Initial full review protocols with YEC-4 decision of "Resubmission for Full Review", the resubmitted protocols will be sent to the initial reviewers

- 5.5.2. Initial full review protocols with a YEC-4 decision of “Resubmission for Expedited review”, the resubmitted protocols will be reviewed by the Member-Secretary or one or both the primary reviewers as decided in the YEC-4 meeting
- 5.5.3. In the case of initial expedited review protocols, the resubmitted protocols will be reviewed by the Member-Secretary or one or both the primary reviewers as opted by the reviewers in the initial expedited review form
- 5.5.4. Exemption from review, the resubmitted protocols will be reviewed by the Member-Secretary

**5.6. The review assessment form:**

- 5.6.1. The reviewers must assess whether each of the clarifications sought by/ recommendations made by YEC-4 is addressed appropriately, included in the resubmission application form and reflected in the updated version of the resubmitted document
- 5.6.2. If one or more of the points have not been appropriately responded to, the reviewer must make a note in the assessment form by entering “Acceptable / Not acceptable”. If entering “Not acceptable” further clarification is required.
- 5.6.3. If additional queries (including new queries) / recommendations are required, the reviewer must make a note in the assessment form
- 5.6.4. The reviewer will also indicate the further review of resubmissions
  - 5.6.4.1. Review by the same reviewer
  - 5.6.4.2. Review by the Member-Secretary
- 5.6.5. Reviewer will also include provisional decision in the form as given below
- 5.6.6. Once the review is completed, the member will forward the completed and signed assessment form to the YEC-4.

**5.7. Provisional decision:** The reviewer will make one of the following decisions:

- 5.7.1. Approved: If all the clarifications/ recommendations have been appropriately responded by the PI
- 5.7.2. Minor modifications: If few points have not been appropriately responded or if additional queries/ recommendations are required
- 5.7.3. Major modifications: If one or more of the points have not been appropriately responded or if additional queries/ recommendations are required or if the justification/ explanation provided by the PI need further deliberation, the reviewer may request for discussion in the YEC-4 meeting
- 5.7.4. Disapproved (with reasons) and referred to YEC-4 meeting for final decision

### 5.8. Final decision:

- 5.8.1. For resubmissions for expedited review, the final decision is made by the Member-Secretary (SOP7B/v1) and ratified in subsequent YEC-4 meeting
- 5.8.2. For resubmission for full review, the final decision is made in the YEC-4 meeting as per SOP7A/v1

### 6. References:

- 6.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017
- 6.2. SOP7A/v1: Initial Full Review of Research Protocols
- 6.3. SOP7B/v1: Expedited Review of Research Protocol

### 7. Annexures

- 7.1. Ann01/SOP9A/v1: Application for resubmission
- 7.2. Ann02/SOP9A/v1: Assessment of resubmitted protocol

#### Ann01/SOP9A/v1:

#### Application for resubmission

<b>Protocol Number:</b> <b>Protocol title:</b> <b>Name of the PI:</b> <b>Department:</b> <b>Date of communication of YEC-4 comments:</b> <b>Resubmission Number:</b>
<b>Type of Resubmission:</b> Resubmission for full review: Resubmission for expedited review: Reviewers:
<b>Documents submitted and the updated version numbers:</b> Protocol Version: Case record form version: PIS version: ICF version: Questionnaire version: <b>Any other: (Specify with version)</b>
<b>Note to the PI: It is the responsibility of the PI to</b> <ol style="list-style-type: none"> <li>1. Respond to every clarification sought /recommendation made by the YEC-4 point by point</li> <li>2. Respond at least one week before the next YEC-4 meeting.</li> <li>3. Highlight all the changes made in the protocol documents, update the version number, insert</li> </ol>

page numbers and reflect these changes in the table given above.

4. If the PI does not wish to/ is unable to make a particular change, then the PI may provide a justification/ explanation for the same.
5. Declare any changes made in the protocol which are not recommended by YEC-4
6. Inform the guide and other members of the research team about all the changes made in the documents and seek their approval before submitting to YEC-4
7. Respond to the YEC-4 comments within a maximum of 180 calendar days, failing which, the protocol will be considered as closed.

**Response of the PI**

S. No	YEC-4 comment (add additional rows for more comments)	PI response	Page number	Reviewer's assessment Acceptable/not acceptable
	Any other changes made in the protocol			
Signature of the PI:				Date
Signature of the Guide:				Date
<b>Decision of the reviewer:</b> <ol style="list-style-type: none"> <li>1. Approved:</li> <li>2. Minor modification</li> <li>3. Major modifications:</li> <li>4. Disapproved (to be discussed in the YEC-4 meeting)</li> </ol>				
Signature of the reviewer				

Ann02/SOP9A/v1:

**Assessment of resubmitted protocol**

Protocol Number:	
Protocol title:	
Name of the PI:	Department:
<b>Assessment of the resubmission:</b> <ol style="list-style-type: none"> <li>1. All the clarifications/ recommendations have been appropriately responded:</li> <li>2. The following points have not been appropriately responded:</li> <li>3. Following are the additional queries/ recommendations:               <ol style="list-style-type: none"> <li>a. .</li> </ol> </li> </ol>	

<p>b. .</p> <p>4. The justification/ explanation is not acceptable:</p>
<p><b>Provisional decision:</b></p> <ol style="list-style-type: none"> <li>1. <b>Approved:</b></li> <li>2. <b>Minor modification</b></li> <li>3. <b>Major modifications:</b></li> <li>4. <b>Disapproved</b></li> </ol>
<p><b>Signature of the Reviewer:</b></p> <p><b>Date:</b></p>

**8. Glossary:**

ICMR: Indian Council of Medical Research

PI: Principal Investigator