

Title: Review of Resubmission of protocol and related documents

SOP Code: SOP9A/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Ravi Vaswani Convenor, YEC-1 SOP Subcommittee	Signature with date:  1/6/23
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Reviewed by:

Dr. Viji Prasad Member, YEC-1 SOP Subcommittee	Signature with date:  01/06/2023
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Approved by:

Dr. Vikran Shetty, Chairperson, YEC-1	Signature with date:  6/6/23
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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date:  7/6/23
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Details of superseded SOP9A

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 and NABH assessment

Details of current SOP9A/v4

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01/07/2023	<ol style="list-style-type: none"> Glossary section added in the SOP Terminologies for decision making have been aligned with the ICMR national guidelines

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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe how the YEC-1 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-1 by the Principal Investigator (PI) in response to clarifications and modifications sought by the YEC-1 in the initial review.
3. **Responsibility:**
 - 3.1. **YEC-1 Chairperson will:**
 - 3.1.1. Ensure that the resubmissions are reviewed in a timely manner
 - 3.2. **YEC-1 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-1 meetings
 - 3.3. **YEC-1 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-1 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-1 in response to clarification sought by the YEC-1 or to the recommendation made by YEC-1 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-1 queries/recommendations (Ann01/SOP9A/v4)
 - 5.2.2. The detailed response of the PI to the query (Ann01/SOP9A/v4)
 - 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-1, 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-1 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-1 meeting.
 - 5.3.3. All resubmissions must be done within 180 calendar days of the last YEC-1 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-1 communication
- 5.5. **Review of the resubmission:**
 - 5.5.1. Initial full review protocols with YEC-1 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-1 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-1 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-1 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-1.

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-1 meeting

5.7.4. **Disapproved (with reasons)** and referred to YEC-1 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/v4) and ratified in subsequent YEC-1 meeting

5.8.2. For resubmission for full review, the final decision is made in the YEC-1 meeting as per SOP7A/v4

6. References:

6.1. ICMR’s National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

6.2. SOP7A/v4: Initial Full Review of Research Protocols

6.3. SOP7B/v4: Expedited Review of Research Protocol

7. Annexures

- 7.1. Ann01/SOP9A/v4: Application for resubmission
- 7.2. Ann02/SOP9A/v4: Assessment of resubmitted protocol

**Ann01/SOP9A/v4:
Application for resubmission**

<p>Protocol Number:</p> <p>Protocol title:</p> <p>Name of the PI:</p> <p>Department:</p> <p>Date of communication of YEC-1 comments:</p> <p>Resubmission Number:</p>
<p>Type of Resubmission:</p> <p style="padding-left: 20px;">Resubmission for full review:</p> <p style="padding-left: 20px;">Resubmission for expedited review:</p> <p style="padding-left: 20px;">Reviewers:</p>
<p>Documents submitted and the updated version numbers:</p> <p style="padding-left: 20px;">Protocol Version:</p> <p style="padding-left: 20px;">Case record form version:</p> <p style="padding-left: 20px;">PIS version:</p> <p style="padding-left: 20px;">ICF version:</p> <p style="padding-left: 20px;">Questionnaire version:</p> <p>Any other: (Specify with version)</p>
<p>Note to the PI: It is the responsibility of the PI to</p> <ol style="list-style-type: none"> 1. Respond to every clarification sought /recommendation made by the YEC-1 point by point 2. Respond at least one week before the next YEC-1 meeting. 3. Highlight all the changes made in the protocol documents, update the version number, insert 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-1 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-1 7. Respond to the YEC-1 comments within a maximum of 180 calendar days, failing which, the protocol will be considered as closed.

Response of the PI

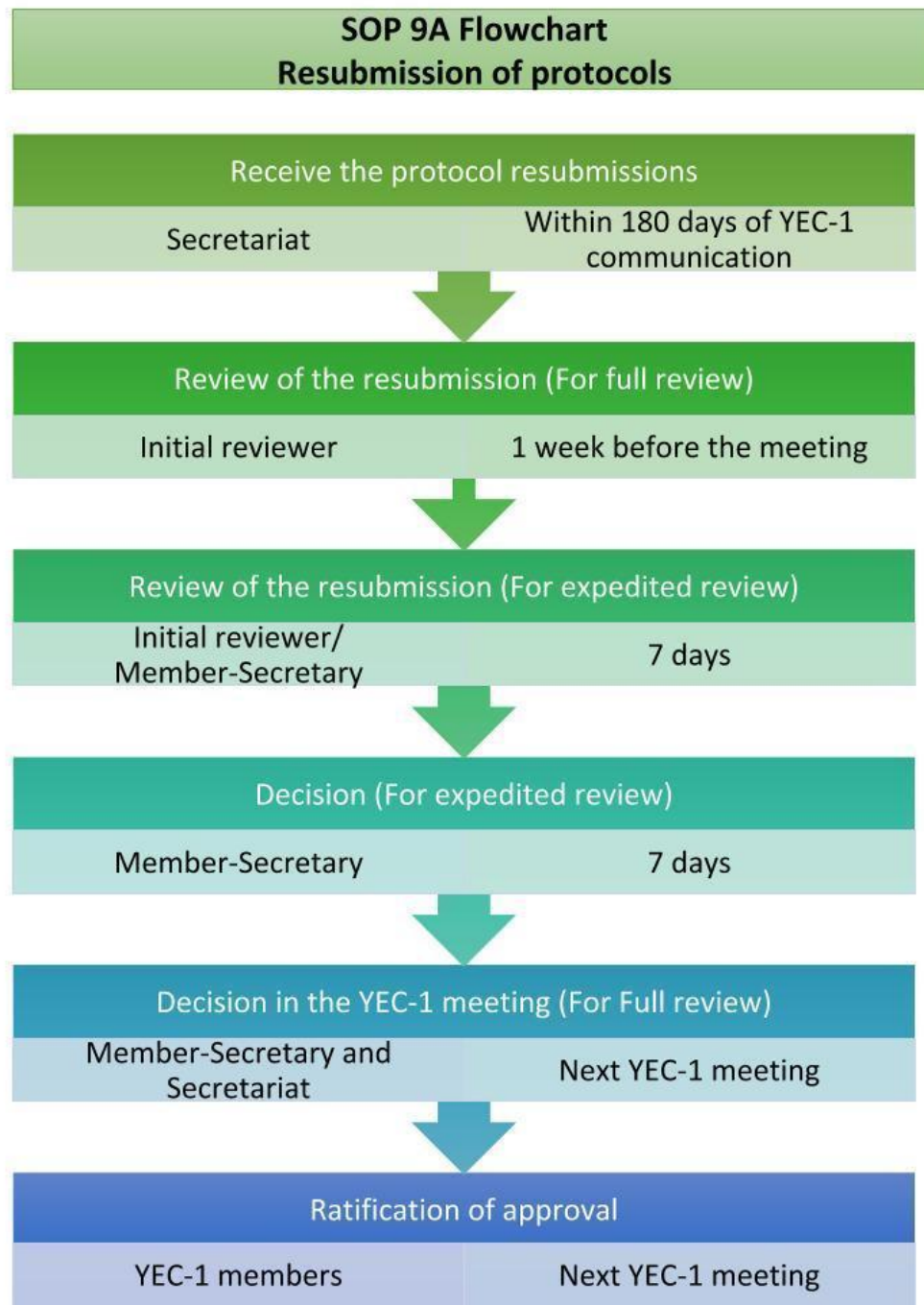
S. No	YEC-1 comment (add additional rows for more comments)	PI response	Page number	Reviewer's assessment Acceptable/not acceptable
	Any other changes made in the protocol			
Signature of the PI:			Date	
Signature of the Guide:			Date	
Decision of the reviewer:				
<ol style="list-style-type: none">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

Ann02/SOP9A/v4:

Assessment of resubmitted protocol

Protocol Number:	
Protocol title:	
Name of the PI:	Department:
Assessment of the resubmission:	
<ol style="list-style-type: none"> 1. All the clarifications/ recommendations have been appropriately responded: 2. The following points have not been appropriately responded: 3. Following are the additional queries/ recommendations: <ol style="list-style-type: none"> a. . b. . 4. The justification/ explanation is not acceptable: 	
Provisional decision:	
<ol style="list-style-type: none"> 1. Approved: 2. Minor modification 3. Major modifications: 4. Disapproved 	
Signature of the Reviewer:	
Date:	

8. Flowchart :



9. Glossary:

ICMR: Indian Council of Medical Research

PI: Principal Investigator