




Title: Review of Resubmission of protocol and related Documents

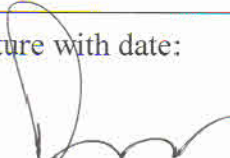
SOP Code: SOP9A/v3

Effective Date: 03/10/2019

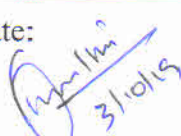
Prepared by:

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

Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date:  3 Oct 19
--	---

Approved by:

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

Notified by:

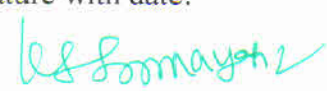
Registrar, Yenepoya deemed to be University	Signature with date:  3/10
---	--

Table of Contents:

Sl No	Content	Page
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Definitions	3
5	Detailed instructions	4
6	References to other SOPs	7
7	Annexures	7
8	Flowchart	10

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) with clarifications and modifications sought by the YEC-1 in the initial review.
3. **Responsibility:**
 - 3.1. The YEC-1 Chairperson will
 - 3.1.1. Ensure that the resubmissions are reviewed in a timely manner
 - 3.2. The 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. The YEC-1 Secretariat will
 - 3.3.1. Check that the completion of the resubmitted documents
 - 3.4. The 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 the protocol refers to the protocol and/or the protocol related documents which are submitted to YEC-1 in response to the 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 resubmissions
 - 4.2. **Resubmission for expedited review:** Any resubmission which is categorized for expedited review after
 - 4.2.1. Initial full review (As decided in the YEC-1 meeting and recorded in the Decision form)
 - 4.2.2. Initial expedited review

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

4.3.1. Initial full review (As decided in the YEC-1 meeting and recorded in the Decision form)

4.3.2. Initial expedited review where the member/members request(s) discussion in the YEC-1 meeting.

5. Detailed instructions

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

5.1.1. The protocol or related documents with changes incorporated

5.1.2. Update the version number for each resubmitted document

5.1.3. Page numbers

5.1.4. Date of resubmission

5.1.5. All changes must be highlighted

5.1.6. Signatures wherever required

5.1.7. Must be submitted within a maximum of 180 days from YEC-1 communication

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

5.2.1. The YEC-1 query/recommendation

5.2.2. The detailed response of the PI to the query

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 resubmission application form must be signed and dated by the PI and the 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 a maximum of 180 calendar days of the last YEC-1 communication, failing which, the protocol submission will be considered as closed.
- 5.3.4. Any resubmission categorized for full review will be included in the subsequent YEC-1 meeting agenda only if it is received at least 10 calendar days before the YEC-1 meeting.
- 5.3.5. The review time for resubmission must be completed within 7 calendar days

5.4. Receipt of the resubmission:

- 5.4.1. The Secretariat will check the resubmission for completeness of the resubmission form
- 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 lead discussants and the other members.
- 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. 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, the reviewer must make a note in the assessment form

5.6.3. If one or more of the points have not been appropriately responded, with a justification or explanation by the PI, the reviewer must assess if it is acceptable and note the same in the assessment form

5.6.4. If additional queries/ recommendations are required, the reviewer must make a note in the assessment form

5.6.5. The reviewer will also indicate the further review of resubmissions

5.6.5.1. Review by the same reviewer

5.6.5.2. Review by the Member-Secretary

5.6.6. The reviewer will also include the provisional decision in the form as given below

5.6.7. 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. **Resubmission:** If one or more of the points have not been appropriately responded or if additional queries/ recommendations are required

5.7.3. **For discussion in the YEC-1 meeting:** 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

5.8. Final decision:

- 5.8.1. For resubmissions for expedited review, the final decision is made by the Member-Secretary as per SOP7B/v3 and ratified in the 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/v3

6. Reference to other SOPs:

- 6.1. SOP7A/v3: Initial Full Review of Research Protocols
- 6.2. SOP7B/v3: Expedited Review of Research Protocol

7. Annexures

- 7.1. Ann01/SOP09/v3: Application for resubmission
- 7.2. Ann02/SOP09/v3: Assessment of resubmitted protocol

**Ann01/SOP09/v3:
Application for resubmission**

Protocol Number:

Protocol title:

Name of the PI:

Department:

Date of communication of YEC-1 comments:

Note to the PI: It is the responsibility of the PI to

- 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
1				
2				
3				
4				
5				
	Any other changes made in the protocol			

Signature of the PI:
Date
Signature of the Guide:
Date

**Ann02/SOP09/v3:
Assessment of resubmitted protocol**

Protocol Number:
Protocol title:
Name of the PI:
Department:

Assessment of the resubmission:

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:
 - a. .
 - b. .
4. The justification/ explanation is not acceptable:

Provisional decision:

1. **Approved:**
2. **Resubmission:**
 - a. To be reviewed by the initial reviewer:
 - b. To be reviewed by the Member-Secretary:
3. **For discussion in the YEC-1 meeting:**

Signature of the Reviewer:

Date:

8. Flowchart :

