Title: Review of Study Completion Reports

SOP Code: SOP13/v1

Effective Date: 20/02/2025

Prepared by:

Mrs. Anju Ullas Member, YEC-3 SOP Subcommittee	Signature with date

Reviewed by:

Dr. Asir John Samuel Convenor, YEC-3 SOP Subcommittee	Signature with Date

Approved by:

Dr. Haripriya S, Chairperson, YEC-3	Signature with Date

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date

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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the review and decision-making of study completion reports submitted by the principal investigators (PI) for protocols approved by Yenepoya Ethics Committee-3 (YEC-3).
2. **Scope:** This SOP applies to the review and decision-making of the study completion report submitted by the PI for study approved by YEC-3.
3. **Responsibility:**
   - 3.1. **YEC-3 Chairperson will:**
     - 3.1.1. Ensure that all completion reports are reviewed in a timely manner
   - 3.2. **YEC-3 Member-Secretary will:**
     - 3.2.1. Assign reviewers for the study completion reports
     - 3.2.2. Review the reviewers comments and sign off on the report
   - 3.3. **YEC-3 Secretariat will:**
     - 3.3.1. Receive the study completion report from the Principal Investigator and check for completeness.
     - 3.3.2. File the study completion report after the review process
     - 3.3.3. Manage the study completion report and archive the file in the designated cupboard once the report is reviewed and signed off.
   - 3.4. **YEC-3 member(s) will:**
     - 3.4.1. Review the study completion report when assigned in a timely manner
   - 3.5. **Principal Investigator will:**
     - 3.5.1. Submit the completion report within a month of data collection completion
     - 3.5.2. Submit the summary report once the data analysis is completed
4. **Detailed instructions:**
   - 4.1. **Receipt of Study Completion Report:**
     - 4.1.1. The study completion report along with a summary of the study is expected from the investigator within 1 month of completion of the study at the site.
     - 4.1.2. The Secretariat will receive the study completion report duly filled and signed by the principal investigator as per the format (Ann01/SOP13/v1).
   - 4.2. **Review of the study completion report:**
     - 4.2.1. The Secretariat will review the study completion report for completeness.
     - 4.2.2. The Secretariat will forward it to Member-Secretary within 3 calendar days.
     - 4.2.3. Member-Secretary will review the Study Completion Report, confirm that it is complete and present it at the subsequent full board meeting.

4.2.4. Member-Secretary will assign appropriate reviewers if required who will review the study completion report.

4.2.5. Member-Secretary will receive from the member, the study completion review form (Ann02/SOP13/v1) and arrange for it to be tabled in the next meeting of YEC-3 (SOP08/v1).

4.3. **During the meeting:**

4.3.1. The Member-Secretary will briefly summarize the study completion reports received. If required the member assigned to review the study completion report may be asked for clarification.

4.3.2. Following discussion, the members may take one of the following decisions:

4.3.2.1. Approve

4.3.2.2. Request information

4.3.2.3. Recommend further action

4.3.3. The decision form is signed by Member-Secretary/Chairperson/member.

4.3.4. The Secretariat will note the decision in the minutes of the meeting

4.4. **Post meeting - documentation and closure of the file:**

4.4.1. If during the review of the study completion report, the reviewer notices a PD/PV/SAE, the same will be handled as per SOP11/v1. In such cases, the file will remain open till the matter is resolved as per SOP11/v1.

4.4.2. After ratification, Member-Secretary will communicate the decision to the PI (Ann03/SOP13/v1) within 7 calendar days.

4.4.3. The Secretariat will file the extract of the minutes in the respective file

4.4.4. The study completion form, the decision from and the summary of the study will be filed in the protocol file.

4.4.5. The Secretariat will update the database soft copy with the study closure date.

4.4.6. The Secretariat will tag the file as “Closed”, archive it in the designated cupboard and dispose of it after the recommended time as per SOP18/v1.

4.4.7. The Secretariat will make the necessary update in the soft copy of the database and set up a reminder for the date when disposal is due.

5. **References:**

5.1. SOP 06/v1: Management of Submission of Protocol and Protocol-Related Documents

5.2. SOP 08/v1: Agenda Preparation, Meeting Procedures and Recording of Minutes

5.3. SOP 11/v1: Review of Protocol Deviations/Violations

5.4. SOP18/v1: Maintenance, archival, retrieval and disposal of protocol-related documents

6. Annexures

Ann01/SOP13/v1: **Study Completion Reporting Form**
Ann02/SOP13/v1: **Study Completion Review Form**
Ann03/SOP13/v1: **Study Closure Communication to PI**

Ann01/SOP13/v1

Study completion reporting form

Study completion reporting Form

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Title of study: .....

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.....

Principal Investigator (Name, Designation and Affiliation): .....

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1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
3. Provide details of:
   a) Total number of study participants approved by the EC for recruitment: .....
   b) Total number of study participants recruited: .....
   c) Total number of participants withdrawn from the study (if any): .....
   Provide the reasons for withdrawal of participants[1] : .....
   .....
   .....
4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) .....
   .....
   .....
5. Describe the main ethical issues encountered in the study (if any) .....
   .....
   .....
   .....
   .....
6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period
   Deviations: ..... Violation: ..... Amendments: .....
7. Describe in brief plans for archival of records / record retention:.....
   .....
   .....
   .....
   .....

[1] *Explanation for the withdrawal of participants whether by self or by the PI*

Version 1.0

8. Is there a plan for post study follow-up? Yes ☐ No☐

If yes, describe in brief: .....

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9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes ☐ No☐

If yes, describe in brief: .....

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10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No☐

If yes, describe in brief: .....

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11. Describe results (summary) with Conclusion [2] : .....

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.....

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12. Number of SAEs that occurred in the study: .....

13. Have all SAEs been intimated to the EC ? Yes ☐ No☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No☐

If yes, provide details.....

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.....

Signature of PI: ..... dd mm yy

[2] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

Version 1.0

Ann02/SOP13/v1
Study completion review form

Protocol No: YEC-3/
Title:

Sl No	Details	Response
1	Comments on the summary of the project	
2	Decision	Approve Request information Recommend further action
3	Signature of the Member-Secretary and date	
4	YEC-3 meeting date in which ratified	
5	Extract of the resolution from the minutes	
6	Signature of Chairperson/ Member-Secretary with date	

Ann03/SOP13/v1
Study Closure Communication to PI

Sub : Study closure : protocol No: YEC-3/----------
Dear Dr/Mr/Ms,
We have reviewed the Study Completion Report and the summary of your protocol (details below):

1	Protocol No.	
2	Title of the study:	
3	Principal investigator:	
4	Co-Investigators (All names)	
5	Department:	
6	Date of approval	

The closure of the study has been ratified in the YEC-3 meeting of --------. The file is closed for all communications. Nevertheless, we would appreciate it if you could send us a copy of the draft manuscript, if and when you choose to publish the results. As per the SOP of YEC-3, the file will be archived in YEC-3 for a further period of 3 years (or 5 years if clinical trial) and then destroyed by shredding. This is for your information.
We hope that you have destroyed and disposed of all samples collected (if any) for the purpose of this research (or ensured that it has been done by the concerned research team member who was handling the samples) as per your approved protocol. In case you haven't, we recommend that you do so, as soon as possible. We recommend that you also destroy the hard and soft copies of the raw data (case record forms) after a specified period (of 3 years for all protocols and 5 years for clinical trials) from the date of this email.

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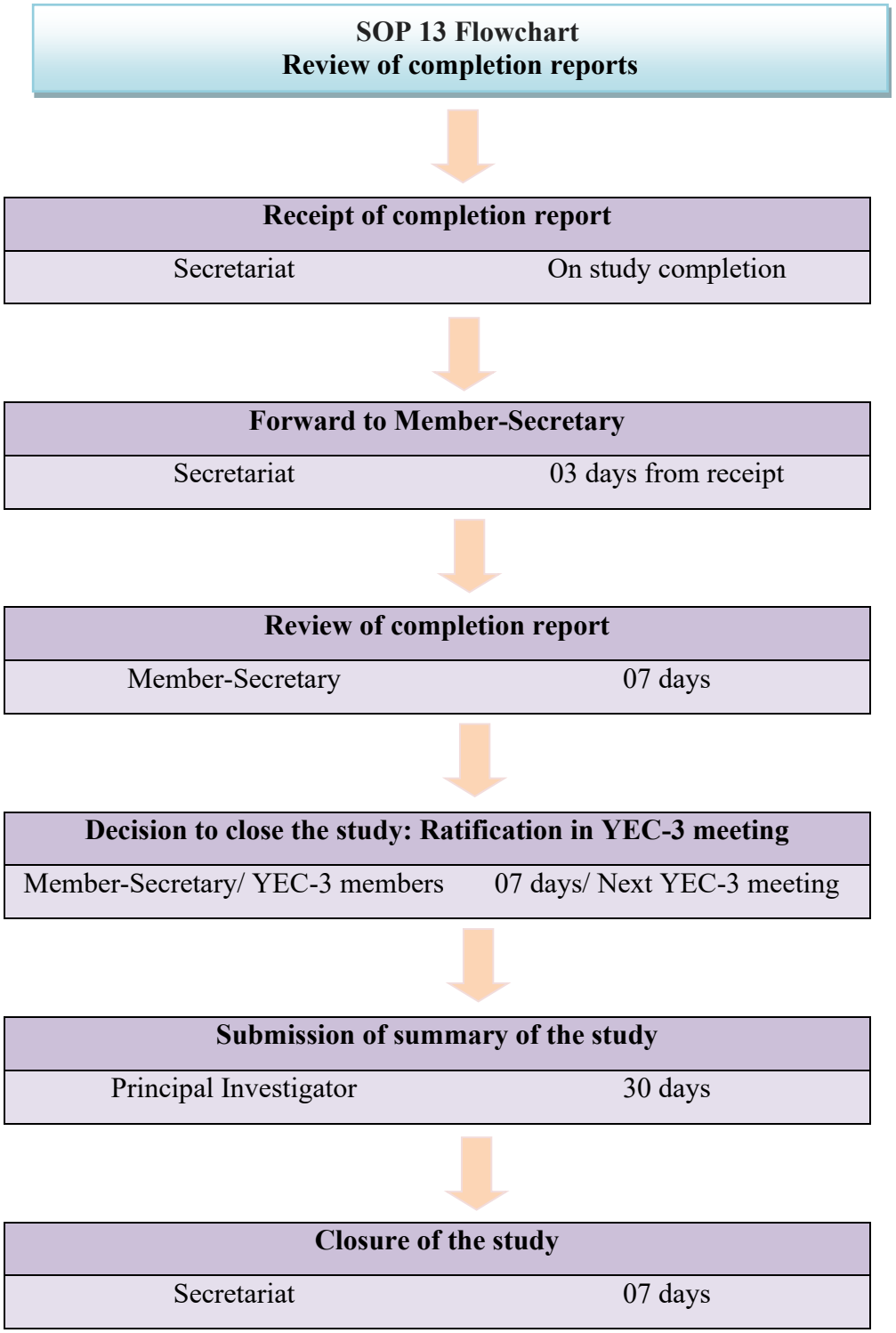
Subject: File closed due to non-communication
Dear Dr. ----
Your research proposal bearing protocol no. ( ) titled **"----------"** has been considered as closed. Since we have not received the status /closure report despite the reminder, this file will be considered closed. For any clarification, email/contact YEC-3.

7. Flowchart


SOP 13 Flowchart
Review of completion reports
Receipt of completion report
Secretariat
On study completion
Forward to Member-Secretary
Secretariat
03 days from receipt
Review of completion report
Member-Secretary
07 days
Decision to close the study: Ratification in YEC-3 meeting
Member-Secretary/ YEC-3 members
07 days/ Next YEC-3 meeting
Submission of summary of the study
Principal Investigator
30 days
Closure of the study
Secretariat
07 days

8. **Glossary:**

PI: Principal Investigator

SAE: Serious Adverse Event

CoI: Conflict of interest