Title: Review of Study Completion Reports

SOP Code: SOP13/v4

Effective Date: 01/07/2023

Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date 1/6/2023

Reviewed by:

Dr. Pooja Harish S Member, YEC-1 SOP Subcommittee	Signature with Date 1/06/2023

Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date 6/6/23

Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date 2/6/23

Details of superseded SOP13

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 SOP13/v4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	1. Glossary section added in the SOP 2. Terminology on the decision on the protocol has been revised 3. Provision for comments of the reviewers added to the assessment form

Table of Contents:

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-1 (YEC-1).
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-1.
3. **Responsibility:**
   - 3.1. **YEC-1 Chairperson will:**
     - 3.1.1. Ensure that all completion reports are reviewed in a timely manner
   - 3.2. **YEC-1 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-1 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-1 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/v4).
   - 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 2 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/v4) and arrange for it to be tabled in the next meeting of YEC-1 (SOP08/v4).

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/v4. In such cases the file will remain open till the matter is resolved as per SOP11/v4.

4.4.2. After ratification, Member-Secretary will communicate the decision to the PI (Ann03/SOP13/v4).

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/v4.

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/v4: Management of Submission of Protocol and Protocol-Related Documents

5.2. SOP 08/v4: Agenda Preparation, Meeting Procedures and Recording of Minutes

5.3. SOP 11/v4: Review of Protocol Deviations/Violations

5.4. SOP18/v4: Maintenance, archival, retrieval and disposal of protocol-related documents

6. **Annexures**

Ann01/SOP13/v4 **Study Completion Report**

Ann02/SOP13/v4: **Study Completion Review Form**

Ann01/SOP13/v4

Study completion reporting form

(Download the form, type the details, print, sign, scan and send to YEC-1 at ethcom@yenepoya.edu.in. Please do not delete any of the text typed in the form)

A. Protocol details			
1	Protocol No.		
2	Title:		
3	Name of the Principal Investigator: Department and Institution:		
4	Name of the guide (*if applicable*): Department and Institution:		
5	Validity of approval by YEC-1	From:	To:
6	Extensions of approval *(add rows for each extension)*	From:	To:
7	Protocol amendment *(add rows for each amendment)*	From:	To:
8	Dates for periodic review		
B. Protocol timelines			
1	Date of initiation of the study:		
2	Date of the last recruitment:		
C. Participant details			
1	Sample size approved		
2	Number of participants screened		
3	Number of screen failures		
4	Number of participants recruited		
5	Number of ongoing participants		
6	Number of completed participants		
7	Number of participants who withdrew the consent	(Provide reasons for withdrawal of consent)	
8	Number of participants discontinued from the study by PI or sponsor	(Provide reasons for discontinuation from study)	
9	Number of participants with AEs	(Provide details of each adverse event)	
10	Number of SAEs reported:	(Provide details of reporting of each SAE)	
D. Changes in the protocol/ risk to participants:			

1	Whether approved protocol version followed:	
2	Any changes made in the selection criteria of participants	
3	Any changes made in the protocol	
4	Any changes made in the study team; any change in guide Any changes in the sample size	
5	Any changes in the funding status	
6	Any increase in the risk to the participants based on the findings of the current study/new information in literature	
E. Monitoring/ data analysis		
1	Has interim data analysis been done and reported earlier?	(If yes, provide the report.)
2	Has the data safety and monitoring board reported?	(If yes, provide the report)
3	Has YEC-1/ regulatory authorities conducted a site monitoring/ audit?	(If yes, provide the report)
F. Any other:		
1	Any investigator(s) have developed a conflict of interest during the conduct of the study	(If yes, provide the report)
2	Any difficulties/ events faced during the study	
3	Any other information you would like to share with the YEC-1	
G. Summary of the study (in 500 words)		
1	Introduction	
2	Objectives	
3.	Material and methods	
4.	Results and analysis	
5.	Discussion	
6.	Conclusion	
7.	Utilization of the results	

Signature of the PI: (with name and date)
Signature of the guide (if any): (with name and date)

Ann02/SOP13/v4
Study completion review form

Protocol No: YEC-1/
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-1 meeting date in which ratified	
5	Extract of the resolution from the minutes	
6	Signature of Chairperson/ Member-Secretary with date	

Ann03/SOP13/v4
Study Closure Communication to PI

Sub : Study closure : protocol No: YEC-1/----------
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-1 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-1, the file will be archived in YEC-1 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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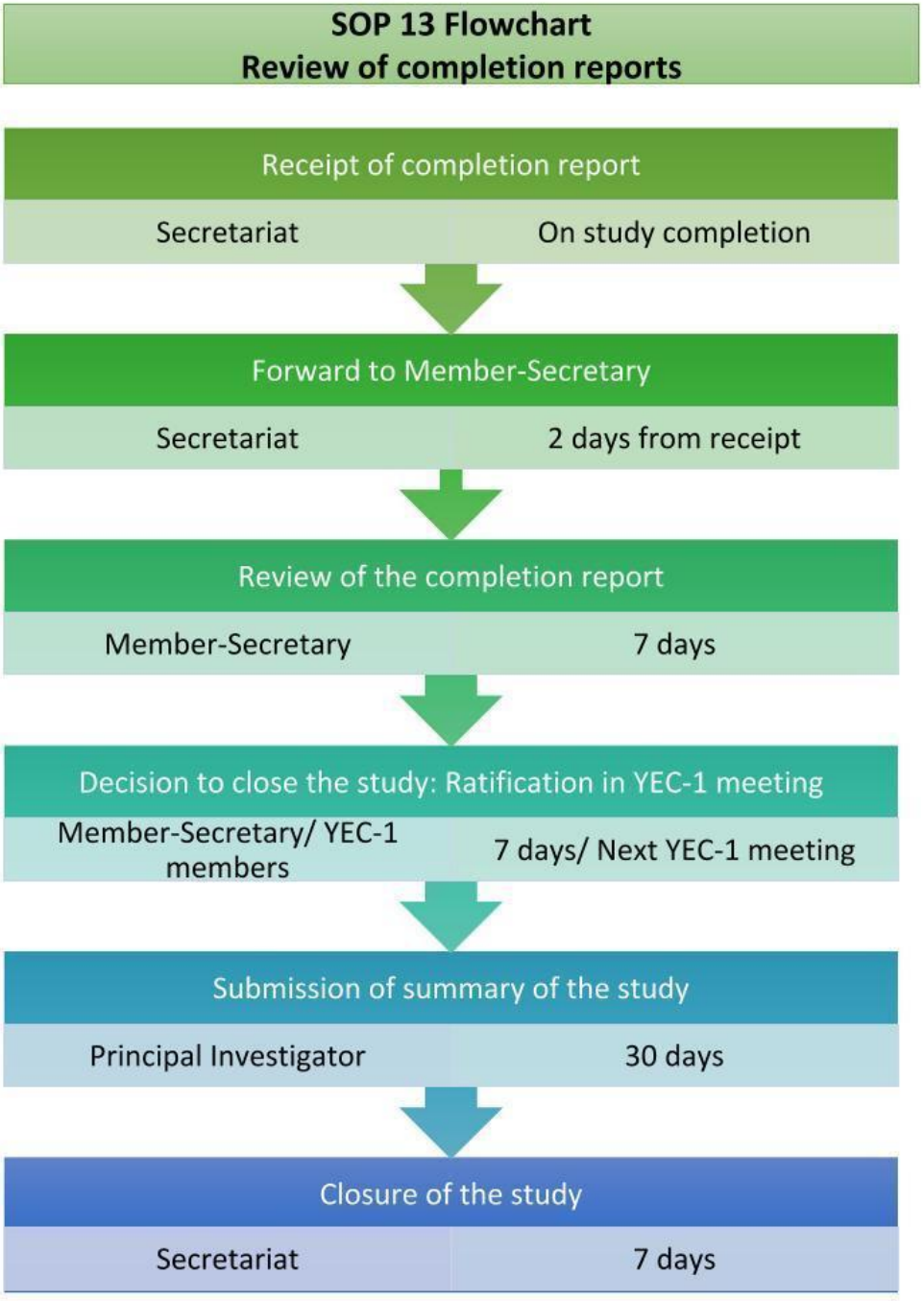
Subject: File closed due to non-communication
Dear Dr. ----
Your research proposal bearing protocol no. ( ) titled **"----------"** has been considered as closed. Since we have not received the status /closure report despite the reminder, this file will be considered closed. For any clarification, email/contact YEC-1.

7. **Flowchart**



8. **Glossary:**

PI: Principal Investigator

SAE: Serious Adverse Event

CoI: Conflict of interest