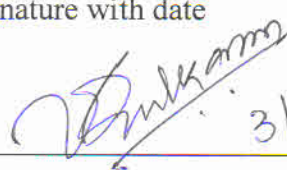


Title: Review of Study Completion Reports


SOP Code: SOP13/v3

Effective Date: 03/10/2019

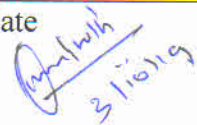
Prepared by:

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

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with Date  3/10/2019
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  3/10/2019
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Notified by:

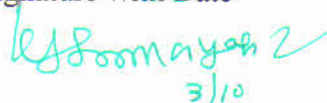
Registrar, Yenepoya deemed to be University	Signature with Date  3/10
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- 1. Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the review and decision-making of study completion reports submitted by the principal investigators (PI) for protocols approved by the 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 studies 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 study completion report within one month of completion of the study
- 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/v3).

4.2. Review of the study completion report:

- 4.2.1. The YEC-1 Secretariat will review the study completion report for completeness.
- 4.2.2. The Secretariat will forward it to the Member-Secretary within 2 calendar days.
- 4.2.3. The 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. The Member-Secretary will assign reviewers if required, who will review the study completion report.
- 4.2.5. The Member-Secretary will receive from the YEC-1 member, the decision form on the study completion report and arrange for the same to be tabled in the next meeting of YEC-1 (SOP08/v3).

4.3. During the YEC-1 meeting:

- 4.3.1. The Member-Secretary will present a collective report for all study completion reports received. If required the YEC-1 member assigned to review the study completion report may be asked for clarification.
- 4.3.2. Following the discussion, the YEC-1 members may take one of the following decisions:
 - 4.3.2.1. Closure report noted, ratified and the study considered closed from the date when the Member-Secretary signed off on the report.
 - 4.3.2.2. Additional information/clarification needed
 - 4.3.2.3. Protocol deviation/violation/SAE noted and the review of the same will be initiated
- 4.3.3. The decision form is signed by the Member-Secretary/Chairperson/ YEC-1 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, Member-Secretary/ Member notices a protocol deviation/violation/SAE, the same will be handled as per SOP11/v3. In such cases the file will remain open till the matter is resolved as per SOP11/v3.
- 4.4.2. After ratification, the Member-Secretary will communicate the decision to the PI.
- 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 soft copy of the database with the study closure date.
- 4.4.6. The Secretariat will tag the file as “Closed” and archive it in the designated cupboard as per SOP18/v3 and then disposed after the recommended time as per SOP18/v3.
- 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. Reference to other SOPs:

1. **SOP 06/v3:** Management of Submission of Protocol and Protocol-Related Documents
2. **SOP 08/v3:** Agenda Preparation, Meeting Procedures and Recording of Minutes
3. **SOP 11/v3:** Review of Protocol Deviations/Violations
4. **SOP18/v3:** Maintenance, archival, retrieval and disposal of protocol-related and other documents

6. Annexures

Ann01/SOP13/v3 **Periodic/Study Completion Report**

Ann01/SOP13/v3 Periodic/Completion Report Form

Part A: To be filled by the Principal Investigator:

SI No	Details	Response
1	YEC-1 Protocol No.	
2	Study title	
3	Name and affiliation of the Principal Investigator:	
4	Total number of study participants recruited	
5	Total number of study participants approved by YEC-1 at start of study	
6	Study duration	
7	Brief summary report with the following headings: Title: Background: Objectives: Brief methodology Results Analysis Discussion Conclusion Note: If the final report is not available from the Sponsor it may be submitted to the YEC-1 as soon as possible.	
8	Number of serious adverse events (SAE) at the study site related to the ethical clearance provided by YEC-1	

9	Whether all SAEs were reported on time to YEC-1	Yes/No Comments
10	Number of participants withdrawn	
11	Reasons for withdrawal	
12	Name and signature of the PI with date	

Part B: To be filled in by the Secretariat YEC-1:

Sl No	Details	Response
1	Action taken	Noted/Approved Require more information/action (please specify):
2	Signature of the Member-Secretary and date	
3	YEC-1 meeting date in which ratified	
4	Extract of the resolution from the minutes	
5	Signature of Chairperson/ Member-Secretary with date	

7. Flowchart

