

**Title:** Review of Study Completion Reports

**SOP Code:** SOP13/v2

**Effective Date:** 01/08/2016

**Prepared by:**

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**Reviewed by:**

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with Date
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**Approved by:**

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date
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**Notified by:**

Registrar Yenepoya University vide Notification No.	Signature with Date
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**Table of Contents:**

<b>No.</b>	<b>Content</b>	<b>Page No.</b>
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Detailed Instructions	3
5	Reference to other SOPs	4
6	Annexures	5
7	Flowchart	7

## **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of study completion report submitted for studies approved by the YenePOYA University Ethics Committee (YUEC).

## **2. Scope**

This SOP applies to the review of the Study Completion Report which is a written report of every completed study submitted by the Principal Investigator (PI).

## **3. Responsibility**

It is the responsibility of the YUEC Secretariat/Chairperson/Member Secretary/ Member(s) to review the study report and act on it.

## **4. Detailed instructions:**

### **4.1 Receipt of Study Completion Report:**

4.1.1 The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format (Ann01/SOP13/v2) from the PI. The study completion report is expected from the investigator within 1 month of completion of the study at the site.

4.1.2 The Secretariat will follow instructions as in SOP06/v2 (Management of Protocol Submission) for receiving and checking the report package.

4.1.3 It is the responsibility of the YUEC Secretariat to review the report for completeness.

4.1.4 The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form (Ann01/SOP13/v2) and forward it to the Member-Secretary within 7 working days of receipt.

4.1.5 The Member-Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

4.1.6 If there is a need felt (e.g. a deviation/ violation is noted), the Member-Secretary will handle it as per SOP11/v2.

4.1.7 The Secretariat shall include the Study Completion Report Form in the agenda for YUEC members as per SOP08/v2 for discussion at the full board meeting

#### **4.2 During the YUEC meeting:**

4.2.1 The Member Secretary will present the report and members can discuss as needed.

4.2.2 Following the discussion, the Chairperson may take one of the following decision:

- Noted/approved
- Request for additional information/clarification

4.2.3 The Secretariat will note the decision in the meeting minutes.

4.2.4 The Member Secretary will draft a letter to the PI conveying decision on the study completion report.

4.2.5 The study shall be considered as closed if the decision by YUEC is “Noted” or “Approved”.

4.2.6 The Secretariat will accept and file the report and get the Study Completion Report Form (Ann01/SOP13/v2) signed by the Chairperson .

4.2.7 The final report will be placed in the master file and kept in the archival area.

4.2.8 YUEC Secretariat will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

#### **5. Reference to other SOPs:**

1. **SOP 06/v2:** Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review
2. **SOP 08/v2:** Agenda Preparation, Meeting Procedures and Recording of Minutes
3. **SOP 11/v2:** Review of Protocol Deviations/Violations

#### **6. Annexures**

Ann01/SOP13/v2 **Study Completion Report**

**Ann01/SOP13/v2  
Study Completion Report Form**

**Part A: To be filled by the Principal Investigator:**

SI No	Details	Response
1	YUEC 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 YUEC at start of study	
6	Study duration	
7	Brief summary report (with conclusions): <i>(Use blank sheet and attach if required)</i>  Note: If the final report is not available from the Sponsor it may be submitted to the YUEC as soon as possible.	
8	Number of serious adverse events (SAE) at the study site related to the ethical clearance provided by YUEC	
9	Whether all SAEs were reported on time to YUEC	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 YUEC:**

SI No	Details	Response
1	Action taken	Noted/Approved Require more information/action (please specify):
2	YUEC meeting date	
3	Extract of the resolution from the minutes	
4	Signature of Member-Secretary with date	

## 7. Flow Chart

No.	Activity	Responsibility
1	Receipt of the study completion report	YUEC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	YUEC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to Member-Secretary	YUEC Secretariat
4	Review of the study completion report for completeness and informing members at YUEC meeting	Member-Secretary/
	Inclusion of the report/ review at meeting	YUEC Secretariat
	Discussion and decision at the meeting	Member Secretary/ Chairperson
	Noting the decision in the minutes of the meeting	YUEC Secretariat
	Conveying decision to the Principal Investigator	YUEC Secretariat
	Archiving all the study-related documents along with the study completion report	Administrative Officer