


**Title:** Review of Study Completion Reports


**SOP Code:** SOP13/v2

**Effective Date:** 15/07/2016

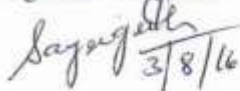
**Prepared by:**

Dr. Ravi Vaswani Member, YUEC	Signature with date  30/7/16
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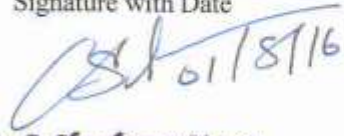
**Reviewed by:**

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with Date  30/07/2016
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**Approved by:**

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date  3/8/16
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**Notified by:**

Registrar Yenepeya University vide Notification No. YUREG/ACA/YUEC/FERCAP/01/2016	Signature with Date  Dr. G. Sreejyoth Menon Registrar Yenepeya University Mangaluru - 675 018
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**Title:** Review of Study Completion Reports

**SOP Code:** SOP13/v2

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

**Prepared by:**

Dr. Ravi Vaswani Member, YEC-1	Signature with date
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**Reviewed by:**

Dr. Uma Kulkarni Jt Secretary, YEC-1	Signature with Date
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Dr. Sayeegeetha Hegde Chairperson, YEC-1	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	4
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 (YEC-1).

## **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 YEC-1 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 YEC-1 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 YEC-1 members as per SOP08/v2 for discussion at the full board meeting

#### **4.2 During the YEC-1 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 YEC-1 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 YEC-1 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	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 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 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:**

SI No	Details	Response
1	Action taken	Noted/Approved Require more information/action (please specify):
2	YEC-1 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	YEC-1 Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	YEC-1 Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to Member-Secretary	YEC-1 Secretariat
4	Review of the study completion report for completeness and informing members at YEC-1 meeting	Member-Secretary/
5	Inclusion of the report/ review at meeting	YEC-1 Secretariat
6	Discussion and decision at the meeting	Member Secretary/ Chairperson
7	Noting the decision in the minutes of the meeting	YEC-1 Secretariat
8	Conveying decision to the Principal Investigator	YEC-1 Secretariat
9	Archiving all the study-related documents along with the study completion report	Administrative Officer