



YENEPOYA

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NAAC Accredited A+ with CGPA3.47

YENEPOYA ETHICSCOMMITTEE 2

DCGI Registration No.: ECR/1337/Inst/KA/2020

DHR registration No.: EC/NEW/INST/2020/1216

Review of Completion

YEC2/SOP 013/v2

Effective Date: 25.02.2023



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Effective Date: 25.02.2023

Title: Review of completion
SOP Code: YEC2/SOP013/v2
Prepared by:

Dr. K. Leena Pramod Convenor, YEC2 SOP committee	Signature with date <i>Leena</i> 25/02/23
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Reviewed by:

Dr. Rashmi Jain Member, YEC2 SOP committee	Signature with Date <i>Rashmi</i> 25/02/2023
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Approved by:

Dr. Animesh Jain Chairperson, YEC2	Signature with Date <i>Animesh</i> 25/02/2023
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Notified by:

Registrar, Yenepoaya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>K. Somayaj</i> 25/02/23
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Registrar
Yenepoaya (Deemed to be University)
University Road, Derlakatte
Bangalore - 575 014

Details of superseded SOP 11/v1

Subcommittee name	Convenor	Version no	Effective date (dd/mm/yy)	Describe the main changes
Mrs. Smitha D		V1	14.06.2018	Major revision in the SOP

Details of Current SOP 11/v2

SOP subcommittee convenor name	Version no	Effective date (dd-mm-yyyy)	Describe the main changes
Dr. Rashmi Jain	v2	25.02.2023	Added Responsibility Added and Modify in the Annexures



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Table of Contents:

YENEPOYA ETHICS COMMITTEE 2

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Table of Contents

No.	Contents	Page No.
1.	Purpose	03
2.	Scope	03
3.	Responsibility	03
4.	Detailed Instructions	04
5.	References	05
6.	Annexures	05
7.	Flowchart	10



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 Ethics Committee 2(YEC 2).

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:

The YEC2 Chairperson will

Ensure that all completion reports are reviewed in a timely manner

The Member-Secretary will

Assign reviewers for the study completion reports

Review the reviewers comments and sign off on the report

The YEC2 member(s) will:

Review the study completion report when assigned in a timely manner

The Secretariat will:

Receive the study completion report from the Principal Investigator and check for completeness.

File the study completion report after the review process

Manage the study completion report and archive the file in the designated cupboard once thereport is reviewed and signed off.



Principal Investigator will:

Submit the completion report within a month of data collection completion

Submit the summary report once the data analysis is completed

4. Detailed instructions:

Receipt of Study Completion Report:

The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format (YEC2/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.

The Secretariat will follow instructions as in YEC2/SOP06/v2 (Management of Protocol Submission) for receiving and checking the report package.

It is the responsibility of the YEC 2 Secretariat to review the report for completeness.

The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form (YEC2/Ann01/SOP13/v2) and forward it to the Member-Secretary within 7 working days of receipt.

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

If there is a need felt (e.g. a deviation/ violation is noted), the Member-Secretary will handle it as per YEC2/SOP11/v2.

The Secretariat shall include the Study Completion Report Form in the agenda for YEC 2 members as per YEC2/SOP08/v2 for discussion at the full board meeting

During the YEC 2 meeting:

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

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

- Noted/approved
- Request for additional information/clarification



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The Secretariat will note the decision in the meeting minutes.

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

The study shall be considered as closed if the decision by YEC 2 is “Noted” or “Approved”.

The Secretariat will accept and file the report and get the Study Completion Report Form (YEC2/Ann01/SOP13/v2) signed by the Chairperson.

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

YEC 2 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. References:

SOP 06/v2: Management of Submission of Protocol and Protocol-Related Documents

SOP 08/v2: Agenda Preparation, Meeting Procedures and Recording of Minutes

SOP 11/v2: Review of Protocol Deviations/Violations

SOP18/v4: Maintenance, archival, retrieval and disposal of protocol-related document

6. Annexures

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

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

YEC2Ann01/SOP13/v2
Study completion reporting form

(Download the form, type the details, print, sign, scan and send to YEC2 at yec2@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:



Review of Completion
YEC2/SOP 013/v2
Effective Date: 25.02.2023

4	Name of the guide (<i>if applicable</i>): Department and Institution:		
5	Validity of approval by YEC2	From:	To:
6	Extensions of approval (<i>add rows for each extension</i>)	From:	To:
7	Protocol amendment (<i>add rows for each amendment</i>)	From:	To:
8	Dates for periodic review		
B .Protocol time lines			
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 YEC2/ 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 YEC2	
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:



YEC2Ann02/SOP13/v2 Study completion review form

Protocol No: YEC2/

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	YEC2 meeting date in which ratified	
5	Extract of the resolution from the minutes	
6	Signature of Chairperson/Member-Secretary with date	

YEC2Ann03/SOP13/v4

Study Closure Communication to PI

Sub: Study closure: protocol No: YEC2/ ----- 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 YEC2 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 YEC2, the file will be archived in YEC2 for a further period of 3 years (or 5 years if clinical trial) and then destroyed by shredding. This is for your information.



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We hope that you have destroyed and dispose do fall 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.

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 YEC2.



8. Flow chart:

