

**YENEPOYA ETHICS COMMITTEE 2**

**YEC2/SOP14/v2  
Termination Suspension  
24.02.2024**

**Title: Termination / Suspension/ Discontinuation of a Research protocol**

**SOP Code: YEC2/SOP14/v2**

**Effective Date: 24.02.2024**

**Prepared by:**

Dr. Sridevi K Member YEC2 SOP Subcommittee	Signature with date <i>Sridevi K</i> 24/02/2024
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**Reviewed by:**

Dr. Hari Kishore Bhat Member YEC2 SOP Subcommittee	Signature with Date <i>HKBhat</i> 24/02/2024
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**Approved by:**

Dr. Animesh Jain Chairperson , YEC2	Signature with Date <i>Animesh Jain</i> 24/02/24
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**Notified by:**

Registrar, Yenepoya (Deemed to be university)	Signature with Date <i>Sobomayon</i> 24/02/24
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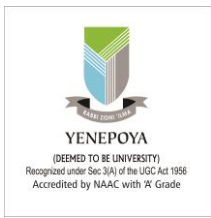
**Details of superseded SOP14/v1**

Registrar  
**YENEPOYA**  
(Deemed to be University)

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

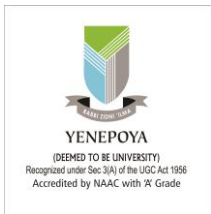
**Details of Current SOP14/v2**

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. K. Leena Pramod	v2	24.02.2024	1. Definition added in the SOP 2. Criteria added in the SOP 3. Reference added in the SOP 4. Glossary section added in the SOP



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## 1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepoya Ethics Committee 2(YEC 2) manages premature termination/suspension/discontinuation of a research study wherein participant enrolment and follow up are discontinued before the scheduled end of the study

## 2. Scope

This SOP applies to any study previously approved by YEC 2 that has been recommended for termination/suspension/discontinuation before its scheduled completion.

## 3. Definitions

**3.1. Termination:** Permanent cessation of all the research-related aspects of a trial, by an external agency such as Data Safety Monitoring Board (DSMB), regulatory authority or YEC-2

**3.2. Suspension:** Temporary cessation of some or all the research-related aspects of a trial, by an external agency such as DSMB, regulatory authority or YEC-2

**3.3. Discontinuation:** Permanent cessation of all the research-related aspects of a trial, by either the sponsor or the principal investigator.

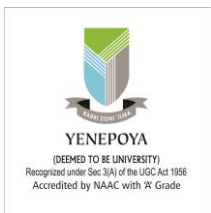
## 4. Criteria for Recommendation of Termination/ Suspension/ Discontinuation

4.1 By PI/Sponsor/Data Safety Monitoring Board/Regulatory authority: Any of these agencies may terminate/suspend a previously approved research when

- In the judgment of these agencies this is appropriate to protect the rights or welfare of participants or
- When new safety information has appeared in the literature, or evolved from this or similar research or
- The sponsor/PI may discontinue the study for logistic or other reasons

### 4.2 By YEC 2:

YEC 2 can prematurely terminate/ suspend a previously approved study in the



following situations:

- Protocol non-compliance/violation following which YEC 2 decides in its meeting to terminate/suspend the study.
- Serious Adverse Events (SAEs) occurring at trial site that may require the study to be prematurely terminated for the safety of the patients.
- When research is not conducted in accordance with YEC 2 policies, or is not in compliance with the local regulations or that has been associated with unexpected/ unanticipated serious harm to participants.

### 5. Responsibility

#### 5.1. YEC-2 Chairperson will:

- Oversee the activities such that timely intervention is carried out and research participants are protected in the best possible manner.

#### 5.2. YEC-2 Member-Secretary will:

- Review the termination/suspension/discontinuation report within 2 calendar days of receiving the decision
- Seek clarification from the PI/Sponsor if required
- Call for and seek approval from the Chairperson for holding an extraordinary meeting, if deemed necessary.
- Communicate the decision of the YEC-2 to the PI/Sponsor/Registrar, Yenepoya deemed to be University

#### 5.3. YEC-2 Secretariat will:

Inform the Chairperson/Member-Secretary about the receipt of a termination/suspension/discontinuation decision within 2 calendar days of the receipt of such report.

### 6. Detailed instructions:

#### 6.1 Receipt of recommendation for study termination:

- The Secretariat will receive the study protocol termination/suspension/discontinuation report submitted by the PI and verify the contents of the report for completeness (YEC2/Ann01/SOP14/v1) and/or

other documents (letter from PI / sponsor), letter from the auditors/SAE sub-committee/YEC-2 meeting decision

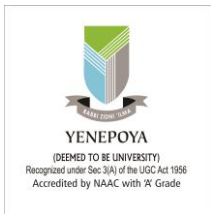
- The Secretariat will inform the Chairperson and Member-Secretary regarding the recommendation for premature termination/suspension/ discontinuation of study protocol and the termination/suspension/ discontinuation report within 2 calendar days of receipt of the report.

### **6.2. Review by YEC 2:**

- The Member-Secretary shall sign and date the study termination/suspension/ discontinuation report in acknowledgement.
- The Member Secretary/Chairperson shall review the report and either call for an extraordinary (emergency) meeting or discuss the report at the regular meeting.
- The Secretariat will arrange for an extraordinary (emergency) meeting or keep matter for discussion at meeting as per YEC2/SOP07A/v1.
- If the premature termination/suspension/discontinuation report is unclear or more information is required from the PI, the Member-Secretary shall seek clarifications/ additional information
- The Member-Secretary in the meeting will inform members about the premature termination/suspension/discontinuation of the project and the reasons for the same.
- If YEC 2 has revoked approval or suspended the study, the regulatory authorities and Registrar of Yenepoya (Deemed to be University) must be informed within 14 working days of the YEC 2 meeting.
- Decision of YEC-1 will be recorded as
  - Approve
  - Request information
  - . Recommend further action

### **6.3 Notifying the Principal Investigator:**

- The Secretariat will prepare a notification letter and send to the PI within 14 working days after the meeting acknowledging the approval of termination or



send a letter seeking clarifications/information regarding the premature termination.

- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 14 days of receiving the letter.
- If the PI does not comply, the matter will be put to the next YEC 2 meeting for discussion. The Member-Secretary will communicate the protocol status and lack of cooperation from the PI to the Registrar, Yenepoya deemed to be University for necessary action.
- The investigator may appeal or respond to the convened YEC 2 communication in writing to the Vice Chancellor, Yenepoya deemed to be University

### **6.4 Storing the protocol document:**

5.4.1 The Secretariat will keep the original version of the premature termination report in the protocol file and archive the file in the appropriate section

5.4.2 The protocol documents will be stored for a period of 5 years from the date of project termination.

### **7. References to other applicable SOPs**

Indian GCP Guidelines 2001

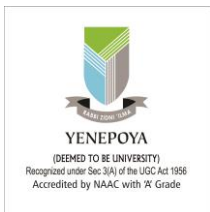
**YEC2/SOP 07A/v1** - Initial Full Review of Research Study Protocols

**8. Annexures:**

YEC2/Ann01/SOP14/v1: Premature Termination Report

**YEC2/Ann01/SOP14/v1**  
**Premature Termination Report**

<b>Sl No</b>	<b>Details</b>	<b>Responses filled by Member-Secretary</b>
1	YEC 2 Protocol Number	
2	Study title	
3	Name and affiliation of Principal Investigator	
4	YEC 2 approval letter no. with date	
5	Date of last/annual/periodic status report submitted to YEC 2	
6	Date of initiation of termination/suspension/ discontinuation (write date when first communication was received either from PI or Sponsor or regulatory authority or YEC 2 member)	
7	Date of communication from Secretariat to Chairperson/ Member-Secretary	
8	Date of conduct of extra-ordinary (emergency) meeting (if any)	
9	Date of correspondence seeking further clarification (if any)	
10	Date of receipt of clarification letter from PI	
11	Termination/suspension/discontinuation initiated by	DSMB/PI/Sponsor/YEC 2
12	Reason for termination/suspension/ discontinuation	
13	Risk possibility to the participants (assessed by Member-Secretary)	Low/Medium/High
12	Study status at time of termination/suspension/ discontinuation a. Participants enrolled b. Participants completed c. Participants on-going d. Drop outs e. Participants yet to be enrolled	



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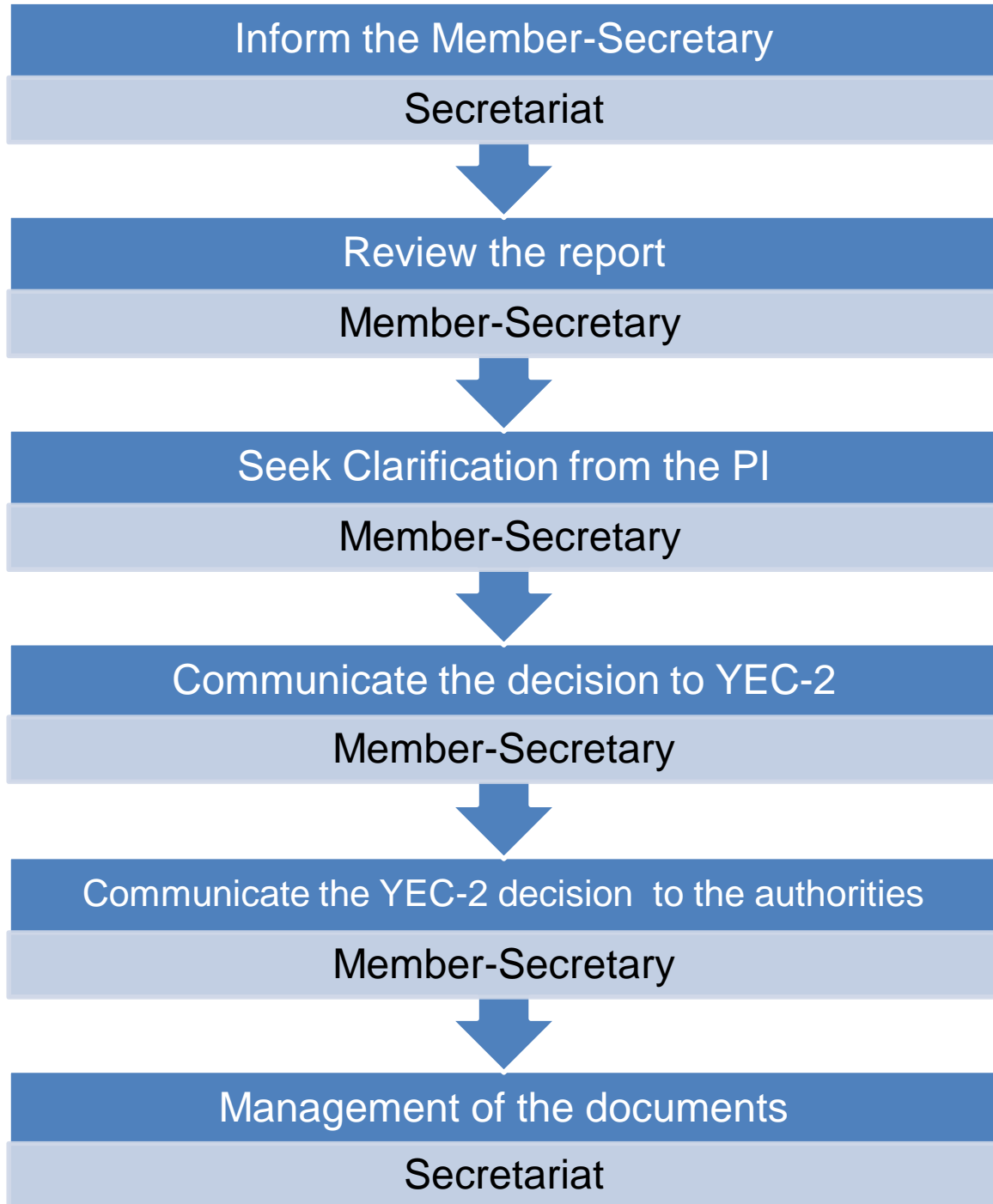
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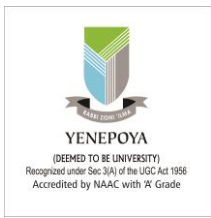
12	Any serious adverse events in the study	Yes/No Comment
13	Whether the SAEs were reported to YEC 2 (on time)	Yes/No Comment
14	Brief summary of the results till date of initiation of termination	
15	Date of YEC 2 meeting where the termination/ suspension/discontinuation matter was discussed  <i>(Note: If termination is recommended close and store the file for five years from this date. If suspension is recommended keep file open till further developments)</i>	
16	Extract of the resolution and the decision of the YEC 2 with regard to the termination/ suspension/discontinuation of the said study	
17	Date and number of the communication to the PI	
18	Date and number of the communication forwarded to the regulatory authority for information	
19	Date of protocol file closure for archiving	

Signature of the Chairperson and date:



**9. Flow Chart**





## **10. Glossary**

GCP: Good Clinical Practice

PI: Principal Investigator

Protocol: Protocol refers to a set of documents that contain the detailed components of the proposed study

Protocol Deviation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in

increased risk to participants  
Protocol Violation: Any research-related activity by the researchers that is different from that mentioned in the approved protocol that may or may not result in increased risk to participants

SAE: Serious Adverse Event