

Title: Termination/Suspension/Discontinuation of a Research Protocol

SOP Code: SOP14/v1

Effective Date: 1.01.2025

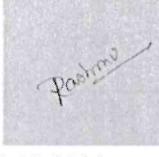
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Dr. Rashmi K S, Chairperson, YEC-4	 22.12.2024 Signature with Date
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Notified by:

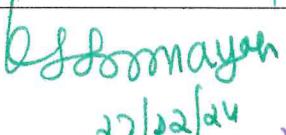
Registrar, Yenepoya (deemed to be University)	 bommayya 27/12/24 Signature with Date <div style="text-align: right; color: purple; margin-top: 10px;"> Registrar YENEPOYA (Deemed to be University) </div>
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1. Purpose:

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepoya Ethics Committee - 4 (YEC-4) 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-4 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 DSMB, regulatory authority or YEC-4
- 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-4.
- 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 for 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
 - 4.1.1. In the judgment of these agencies this is appropriate to protect the rights or welfare of participants or
 - 4.1.2. When new safety information has appeared in the literature, or evolved from this or similar research.
 - 4.1.3. The sponsor/PI may discontinue the study for logistic or other reasons.
- 4.2. By YEC-4: YEC-4 can prematurely terminate/suspend a previously approved study in the following situations:
 - 4.2.1. Protocol non-compliance/violation or occurrence of SAEs following which YEC-4 decides in its meeting to terminate/suspend the study
 - 4.2.2. When research is not conducted in accordance with YEC-4 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-4 Chairperson will:

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

5.2. YEC-4 Member-Secretary will:

- 5.2.1. Review the termination/suspension/discontinuation report within 2 calendar days of receiving the decision
- 5.2.2. Seek clarification from the PI/Sponsor if required
- 5.2.3. Call for and seek approval from the Chairperson for holding an extraordinary meeting, if deemed necessary.
- 5.2.4. Communicate the decision of the YEC-4 to the PI/Sponsor/Registrar, Yenepoya deemed to be University

5.3. YEC-4 Secretariat will:

- 5.3.1. 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:

- 6.1.1. The Secretariat will receive the study protocol termination/suspension/ discontinuation report submitted by the PI/other agencies and verify the contents of the report for completeness (Ann01/SOP14/v1) and/or other documents (letter from PI/sponsor), letter from the auditors/SMV/SAE sub-committees/YEC-4 meeting decision.
- 6.1.2. 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-4:

- 6.2.1. The Member-Secretary shall sign and date the study termination/suspension/ discontinuation report in acknowledgement.
- 6.2.2. The Member Secretary/Chairperson shall review the report and either call for an extraordinary meeting or discuss the report at the regular meeting.
- 6.2.3. The Secretariat will arrange for an extraordinary meeting or keep the matter for discussion at the next regular meeting as per SOP08/v1.
- 6.2.4. 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.
- 6.2.5. In the meeting, the Member-Secretary will inform members of the premature termination/suspension/discontinuation of the study and reasons for the same.

6.2.6. If YEC-4 has revoked the approval or suspended the study, the regulatory authorities and Yenepoya deemed to be University, must be informed within 14 calendar days of the YEC-4 meeting.

6.2.7. Decision of YEC-4 will be recorded as follows:

- 6.2.7.1. Approve
- 6.2.7.2. Request information
- 6.2.7.3. Recommend further action

6.3. Communications from YEC-4:

6.3.1. The Secretariat will prepare a letter and send to the PI within 14 calendar days after the meeting acknowledging the approval of termination or send a letter seeking clarifications/information regarding the premature termination.

6.3.2. In case a letter is sent seeking clarifications/information regarding the premature termination/suspension/discontinuation, the PI shall reply with a written response within 14 calendar days of receiving the letter.

6.3.3. If the PI does not comply, the matter will be put to the next YEC-4 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.

6.3.4. The investigator may appeal or respond to the YEC-4 communication in writing to the Vice Chancellor, Yenepoya deemed to be University.

6.4. Storing the protocol document:

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

6.4.2. 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

SOP08/v1 - Meeting, agenda and minutes of the meeting

8. Annexures:

Ann01/SOP14/v1: Premature Termination Report

Ann01/SOP14/v4

Premature Termination Report

SI No	Details	Responses filled by Member-Secretary
1	YEC-4 Protocol Number	

2	Study title	
3	Name and affiliation of Principal Investigator	
4	YEC-4 approval letter no. with date	
5	Date of last periodic report submitted to YEC-4	
6	Date of initiation of termination/suspension/ discontinuation (write date when first communication was received either from PI, Sponsor, regulatory authority, YEC-4 member)	
7	Date of communication from the Secretariat to Chairperson/ Member-Secretary	
8	Date of conduct of extraordinary meeting (if any)	
9	Date of dispatch seeking more clarification (if any)	
10	Date of receipt of clarification letter from PI	
11	Termination/suspension/discontinuation initiated by	DSMB/PI/Sponsor/YEC-4
12	Reason for termination/suspension/ discontinuation	
13	Risk possibility to the participants (assessed by Member-Secretary)	Low / Medium / High
14	Any serious adverse events in the study	Yes/No Comment
15	Whether the SAEs were reported to YEC-4 (on time)	Yes/No Comment
16	Brief summary of the results till date of initiation of termination	
17	Date of YEC-4 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>	
18	Decision of YEC-4: 1. Approve 2. Request information 3. Recommend further action	
18	Extract of the resolution and the decision of the YEC-4 with regard to the termination/ suspension/discontinuation of the said study	
19	Date and number of the communication to PI	
20	Date and number of the communication to	

	regulatory authority for information	
21	Date of protocol file closure for archiving	

Signature of the Member-Secretary/Chairperson and date:

9. 8. 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

