Title: Termination/Suspension/Discontinuation of a Research Protocol

SOP Code: SOP14/v1

Effective Date: 20/02/2025

Prepared by:

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Approved by:

Dr Haripriya S Chairperson, YEC-3	Signature with Date

Notified by:

Registrar, Yenepoya (deemed to be University	Signature with Date

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1. **Purpose:**

1.1. The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepoya Ethics Committee - 3 (YEC-3) 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 approved by YEC-3 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-3

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-3.

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 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-3: YEC-3 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-3 decides in its meeting to terminate/suspend the study

4.2.2. When research is not conducted in accordance with YEC-3 policies, or is not in compliance with the local regulations or that have been associated with unexpected/ unanticipated serious harm to participants.

5. **Responsibility:**

5.1. **YEC-3 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-3 Member Secretary will:**

5.2.1. Review the termination/suspension/discontinuation report within 3 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 to hold an extraordinary meeting, if deemed necessary.

5.2.4. Communicate the decision of the YEC-3 to the PI/Sponsor/Registrar, Yenepoya deemed to be University

5.3. **YEC-3 Secretariat will:**

5.3.1. Inform the Chairperson/Member-Secretary about the receipt of a termination/suspension/discontinuation decision within 3 calendar days of 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-3 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 3 calendar days of receipt of the report.

6.2. **Review by YEC-3:**

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 clarification/ 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-3 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-3 meeting.

6.2.7. The decision of YEC-3 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-3:**

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-3 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-3 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/Suspension/ Discontinuation Reporting Form

Ann01/SOP14/v1
Premature Termination/Suspension/ Discontinuation Reporting Form

Premature Termination/Suspension/ Discontinuation Reporting Form

Yenepoya Ethics Committee-3 (YEC-3)

EC Ref. No. *(For office use)*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

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1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: .....

   .....

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   .....

   Action taken post Termination/ Suspension/Discontinuation (if any): .....

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5. Plans for post study follow up/withdrawal[1] (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: .....Screened: ..... Screen failures:.....

   Enrolled:..... Consent Withdrawn:..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI:..... Reason(Give details): .....

   .....

[1] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

Version 1.0

Active on treatment: ..... Completed treatment : ..... Participants on follow-up: .....

Participants lost to follow up: ..... Any other: ..... Number of drop outs:.....

Reasons for each drop-out: .....

.....

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.....

7. Total number of SAEs reported till date in the study: .....

Have any unexpected adverse events or outcomes observed in the study been reported to the EC? Yes ☐ No☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No☐

If yes, provide details:.....

.....

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No☐

If yes, have you implemented that suggestion? Yes ☐ No☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? Yes ☐ No☐

(e.g., making arrangements for medical care of research participants): If Yes, provide details

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Summary of results (if any): .....

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.....

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.....

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Signature of PI: ..... dd mm yy

Version 1.0

9. **Flowchart**

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