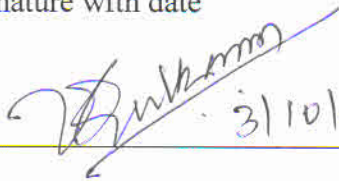


Title: Management Termination/Suspension/Discontinuation of a Research Protocol


SOP Code: SOP14/v3

Effective Date: 03/10/2019

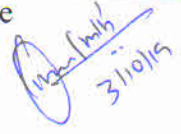
Prepared by:

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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  31/10/19
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Notified by:


Registrar Yenepoya deemed to be University	Signature with Date  3/10
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1. Purpose:

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to describe how YenePOYA Ethics Committee - 1 (YEC-1) manages premature termination/suspension/discontinuation of a research study.
- 1.2. Protocols may be terminated/suspended/discontinued at the recommendation of YEC-1, Data Safety Monitoring Board (DSMB), Principal Investigator (PI), Sponsor, Regulator or other authorized bodies 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-1 that has been recommended for termination/suspension/discontinuation before its scheduled completion.

3. Glossary of terms:

- 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-1
- 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-1.
- 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: The principal investigator/sponsor/data safety monitoring board/regulatory authority may put on hold a previously approved research when
 - 4.1.1. In the judgment of the investigator/sponsor/data safety monitoring board/regulatory authority 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
 - 4.1.3. When new safety information has evolved from this or similar research.
- 4.2. By YEC-1: YEC-1 can prematurely terminate/suspend/discontinue a study in the following situations:
 - 4.2.1. Protocol non-compliance/violation following which YEC-1 decides in its meeting to terminate/suspend/discontinue the study.
 - 4.2.2. Occurrence of SAEs in the on-site trial that may require the study to be prematurely terminated for the safety of the patients.

- 4.2.3. When research is not conducted in accordance with YEC-1 policies, or is not in compliance with the local regulations or that has been associated with unexpected/ unanticipated serious harm to participants.
- 4.2.4. When there is significantly low accrual over long-term as determined by the Member-Secretary/Chairperson (note that suspended protocols remain open and require continuing review).
- 4.2.5. YEC-1 may revoke approval and recommend to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

5. Responsibility: It is the responsibility of YEC-1 to manage the termination of any study previously recommended by it (recommended for termination by DSMB, PI, Sponsor or other authorized bodies or by YEC-1).

5.1. YEC-1 Chairperson will:

- 5.1.1. Oversee the activities of the Member-Secretary and the YEC-1 Secretariat such that timely intervention is carried out and research participants are protected in the best possible manner.

5.2. YEC-1 Member-Secretary will:

- 5.2.1. Review the termination/suspension/discontinuation report within 2 calendar days of receiving it from the YEC-1 Secretariat.
- 5.2.2. Seek clarification from the PI/Sponsor if required
- 5.2.3. Communicate the decision of the YEC-1 to the PI/Sponsor/Registrar, Yenepoya deemed to be University

5.3. YEC-1 Secretariat will:

- 5.3.1. Inform the Chairperson/Member-Secretary about the receipt of a termination/suspension/ discontinuation report within 2 calendar days of the receipt of such report.
- 5.3.2. Be responsible for the management of the premature termination/suspension/ discontinuation process.

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 and verify the contents of the report for completeness (Ann01/SOP14/v3) and/or other documents (letter from PI/sponsor).

6.2. Review by YEC-1:

6.2.1. 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.

6.2.2. The Chairperson/Member-Secretary shall sign and date the study termination/suspension/discontinuation report in acknowledgement.

6.2.3. The Member Secretary/Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular meeting.

6.2.4. The Secretariat will arrange for an emergency (extraordinary) meeting or keep the matter for discussion at the next regular meeting as per SOP7A/v3.

6.2.5. 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 from the Principal Investigator.

6.2.6. In the meeting, the Member-Secretary will inform members of the premature termination/suspension/discontinuation of the project and the reasons for the same.

6.2.7. If YEC-1 has revoked the approval or suspended the study, the regulatory authorities and Yenepeya deemed to be University, must be informed within 14 calendar days of the YEC-1 meeting.

6.3. Communications from YEC-1:

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 will 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 Member-Secretary's letter.
- 6.3.3. If the PI does not comply, the matter will be put to the next YEC-1 meeting for discussion.
- 6.3.4. The Member-Secretary will communicate the protocol status and lack of cooperation from the PI to the Registrar, Yenepoya deemed to be University
- 6.3.5. The investigator may appeal or respond to the YEC-1 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

SOP7A/v3 - Initial Full Review of Research Study Protocols

8. Annexures:

Ann01/SOP14/v3: Premature Termination Report

Ann01/SOP14/v3 Premature Termination Report

Sl No	Details	Responses to be filled in by Member-Secretary/Secretariat
1	YEC-1 Protocol Number	
2	Study title	
3	Name and affiliation of Principal Investigator	
4	YEC-1 approval letter no. with date	
5	Date of last/annual/periodic status report submitted to YEC-1	
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-1 member)	

7	Date of communication from the Secretariat to Chairperson/ Member-Secretary	
8	Date of conduct of extraordinary (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-1
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-1 (on time)	Yes/No Comment
16	Brief summary of the results till date of initiation of termination	
17	Date of YEC-1 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	Extract of the resolution and the decision of the YEC-1 with regard to the termination/suspension/discontinuation of the said study	
19	Date and number of the communication to the PI	
20	Date and number of the communication forwarded to the regulatory authority for information	
21	Date of protocol file closure for archiving	

Signature of the Member-Secretary/Chairperson and date:

9. Flowchart

