

Title: Management of Premature Termination / Suspension / Discontinuation of the Study

SOP Code: SOP14/v2

Effective Date: 01/08/2016

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Approved by:

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date
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Notified by:

Registrar Yenepoya University vide Notification No. YU/REG/ACA/YUEC/FERCAP/01/2016 dated 01/08/2016	Signature with Date
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Yenepeya University Ethics Committee (YUEC) manages premature termination/suspension/discontinuation of a research study.

Protocols may be terminated/suspended/discontinued at the recommendation of YUEC, 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 YUEC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

3. Responsibility

It is the responsibility of YUEC to manage the termination of any study (recommended for termination by Data Safety and Monitoring Board, Principal Investigator, Sponsor or other authorized bodies or by YUEC that has previously approved the protocol. The Secretariat is responsible for management of the premature termination/suspension/ discontinuation process.

4. Recommendation for Termination/ Suspension/ Discontinuation

4.1 By PI/Sponsor:

An investigator/Sponsor may put on hold a previously approved research when in the judgment of the investigator/Sponsor 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.

4.2 By YUEC:

YUEC members/Chairperson can prematurely terminate/ suspend/ discontinue the study in the following situations:

- Protocol non-compliance/violation following which YUEC decides in its meeting to terminate/suspend/discontinue the study.
- 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 YUEC policies, or is not in compliance with the local regulations or that has been associated with unexpected/unanticipated serious harm to participants.
- Zero accrual for 1-2 years or long-term low accrual. Suspended protocols remain open and require continuing review.
- YUEC 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. Detailed instructions:

5.1 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 (Ann01/SOP14/v2) and/or other documents (letter from PI / sponsor).

5.2. Review by YUEC:

- 5.2.1 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 3 working days of receipt of the report.
- 5.2.2 The Member Secretary/Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular meeting.
- 5.2.3 The Secretariat will arrange for an emergency meeting/ keep matter for discussion at meeting as per SOP07A/v2.
- 5.2.4 The Member-Secretary in the meeting will inform members of the premature termination/suspension/discontinuation of the project and the reasons for the same.
- 5.2.5 If the premature termination/suspension/discontinuation report is unclear or more information is required from the PI, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- 5.2.6 The Chairperson shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.

5.2.7 If YUEC has revoked approval/suspended the study, the regulatory authorities and Registrar of Yenepoya University must be informed within 14 working days of the YUEC meeting.

5.3 Notifying the Principal Investigator:

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

5.3.2 In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 60 days of receiving the letter.

5.3.3 If the PI does not comply, the matter will be put to the next YUEC meeting for discussion.

5.3.4 The investigator may appeal or respond to the convened YUEC in writing.

5.4 Storing the protocol document:

5.4.1 The Secretariat will keep the original version of the premature termination report in the protocol file and send the file to the archive.

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

6. References to other applicable SOPs

SOP 07A/v2 - Initial Full Review of Research Study Protocols

Annexures:

Ann01/SOP14/v2: Premature Termination Report

**Ann01/SOP14/v2
Premature Termination Report**

Sl No	Details	Responses
1	YUEC Protocol Number	
2	Study title	
3	Name and affiliation of Principal Investigator	
4	YUEC approval letter no. with date	
5	Date of last/annual/periodic status report submitted to YUEC	
6	Date of initiation of termination/suspension/discontinuation (write date when first communication was received either from PI or Sponsor or regulatory authority or YUEC member)	
7	Date of communication 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	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	
12	Any serious adverse events in the study	Yes/No Comment
13	Whether the SAEs were reported to YUEC 9on time)	Yes/No Comment

14	Brief summary of the results till date of initiation of termination	
15	Date of YUEC 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 YUEC 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:

7. Flow Chart

No.	Activity	Responsibility
1	Ensuring Training of YUEC members	Chairperson/Member-Secretary
2	Training of Secretariat	YUEC Member-Secretary/ Members
3	Assessment of performance of members	YUEC Chairperson
4	Assessment of performance of Chairperson	YUEC Chairperson (self assessment)