



**IHEC – MGMCRI SOPs
Management of Premature Termination /
Suspension / Discontinuation of the Study**

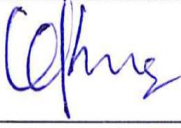

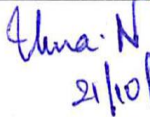

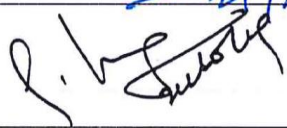


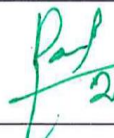
**SOP Code: SOP 14/V2
Effective from 21/10/2019**

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

SOP Code: SOP 14/V2

Effective Date: 21-10-2019

SOP Constitution and Approval

Prepared by:	Signature and Date:
Dr. Lokesh. S, IHEC Member	 21/10/19
Dr. Siva Ranganathan Green, Member Secretary, IHEC	 21/10/19
Dr. Uma Narayanamurthy, Additional Member Secretary, IHEC	 21/10/19
Reviewed by:	Signature and Date:
Dr. Ananthakrishnan. N, IHEC Member	 21/10/19
Dr. Sivagnanam G, IHEC Co-Chairperson	 21/10/19
Approved by:	Signature and Date:
Dr. Jambulingam, P IHEC Chairperson	 21.10.19
Dr. Adithan C, Dean Research, SBV	 21/10/19
Dr. Ravishankar M, Dean, MGMCRI	 21/10



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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Human Ethics Committee (IHEC) manages premature termination/suspension/discontinuation of a research study.

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

3. Responsibility

It is the responsibility of the IHEC 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 the IHEC) that the IHEC has previously approved. 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 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 IHEC

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

- Protocol non-compliance/violation following which IHEC decides in full board meeting to terminate/ suspend/ discontinue the study.



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- SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
- When research is not conducted in accordance with IHEC policies, is not in compliance with the local regulations or that has been associated with unexpected serious harm to participants.
 - Zero accrual for 1-2 years or long-term, low accrual.
- Suspended protocols remain open and require continuing review.
- IHEC may revoke approval and recommend to stop permanently all activities in previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.
- In case the study is terminated by PI/QCO (Quality Control Officer) should give a written explanation to the IHEC in one month.

5. Detailed instructions

5.1. Receipt of Recommendation for Study Termination.

- Secretariat will receive study protocol termination/suspension/discontinuation report submitted by PI and verify the contents of report for completeness (AX 01/ SOP 14/V2) and/or other documents (letter from PI / sponsor).

5.2. Review by the IHEC

- Secretariat will inform Chairperson and Member Secretary/Additional Member Secretary regarding recommendation for premature termination/ suspension/ discontinuation of study protocol and termination/ suspension/ discontinuation report within 3 working days of receipt of report.
- Member Secretary/Additional Member Secretary / Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular full board meeting.
- Secretariat will arrange for an Emergency meeting/ keep matter for discussion at full board meeting as per SOP 07A/V2.
- Member Secretary/Additional Member Secretary in the meeting will inform members of the premature termination/suspension/ discontinuation of the project and the reasons for the same.



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- 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.
- Chairperson shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.
- If the IHEC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days of the full board meeting.

5.3 Notifying the Principal Investigator

- 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.
- 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.
- If the PI does not comply, the matter will be put to the full board meeting for discussion.
- The investigator may appeal or respond to the convened IHEC in writing.

5.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file to archive.
- 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 – Full-Board Review of Research Study Protocols

7. Annexure

Annexure 1: AX 01/ SOP 14/V2- Premature Termination Report



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**Annexure 1: AX 01/ SOP 14/V2
Premature Termination Report**

MGMCRI-IHEC Ref. No. (for office use):

IHEC Protocol no			
Protocol title:			
Principal Investigator:			
Department:			
IHEC approval date:		Date of last Annual/ Periodic status report submitted to IHEC:	
Date of initiation of Study:		Termination/suspension /discontinuation date:	
No. of participants enrolled:		No. of participants completed:	
No. of ongoing participants:		No. of drop outs:	
		Reason for each drop-out:	
SAEs (total no.):	Whether SAEs were reported to the IHEC?		
	Yes	No	
Brief summary of results: (use extra blank paper, if more space is required)			

Reason/s for termination/suspension/discontinuation:

Signature of Principal Investigator with date :

Discussed at the IHEC meeting held on :

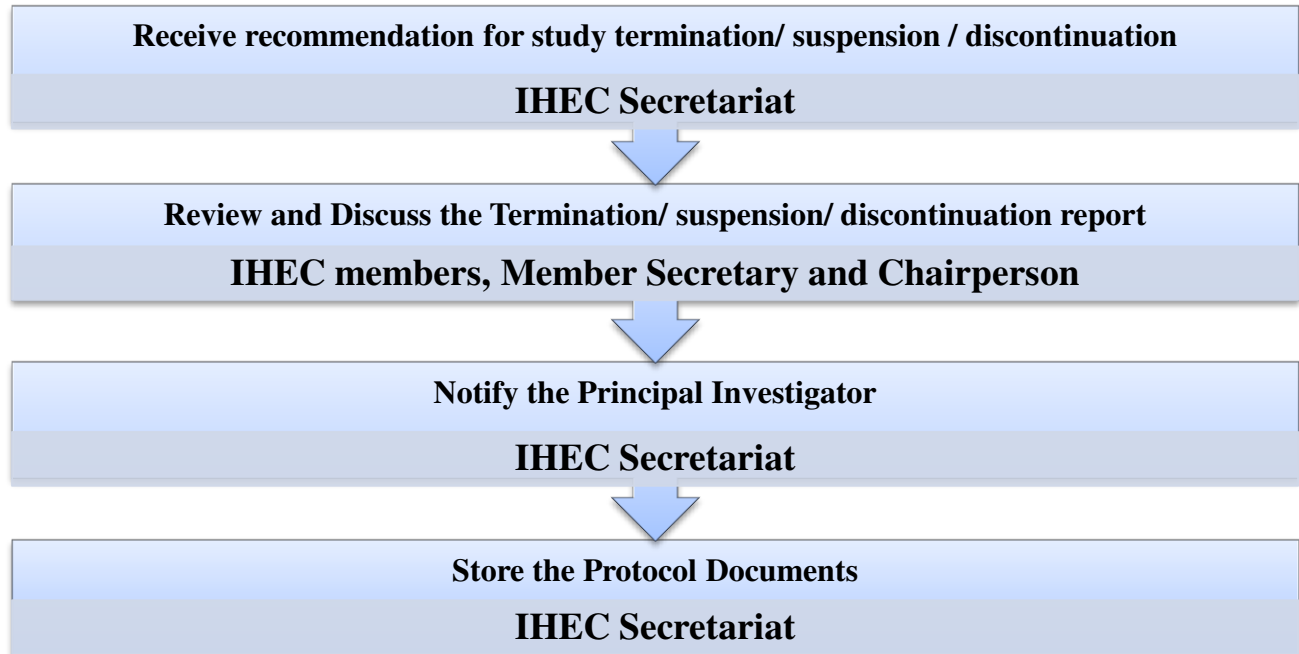
Action taken:

- Approval of Premature Termination / suspension / discontinuation of project:
- Requires more information/ action as follows:

Signature of Chairperson, IHEC with date:



7. Flowchart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*
