

	Institutional Ethics Committee Title: Management of Premature Termination / Suspension / Discontinuation of the study	SOP 14/V1 Effective from September 2019 Valid till September 2022
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14.1. Purpose

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

14.2. Scope

This SOP applies to any study previously approved by the IEC that has been recommended for termination/suspension/discontinuation before its scheduled completion.

14.3. Responsibility

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

14.4. Recommendation for Termination/ Suspension/ Discontinuation

14.4.1 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.

14.4.2 by IEC

IEC can prematurely terminate/ suspend/ discontinue the study in the following situations:

- Protocol non-compliance/violation following which IEC decides in full committee meeting to terminate/ suspend/ discontinue the study.
 - SAEs occurring at trial site may require the study to be prematurely terminated for the safety of the patients.

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- When research is not conducted in accordance with IEC policies, is not in compliance with the local regulations or it has been associated with unexpected serious harm to participants.
- Zero accrual or low accrual for 1-2 years.
- Suspended protocols remain open and require continuing review.
- The IEC may revoke approval and terminate previously approved research protocol which will now be considered closed no longer requiring continuing review.

14.5. Detailed instructions

14.5.1. Receipt of Recommendation for Study Termination.

The Secretariat will receive the study protocol termination/suspension/discontinuation report and verify the contents of the report for completeness and/or other documents like letter from PI/ sponsor.

14.5.2. Review by the IEC

- The Secretariat will inform the Chairperson and Member Secretary regarding the recommendation for premature termination/ suspension/ discontinuation of study protocol and submit the report within 3 working days of receipt of the same.
- The Chairperson shall review the report and either call for an emergency meeting or discuss the report at the regular full committee meeting and the Secretariat will make arrangement accordingly.
- The Member Secretary in the meeting will inform members the reasons for the premature termination/ suspension/ discontinuation of the project.
- If the 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.
- The Chairperson shall acknowledge by signing with date the study termination/ suspension/ discontinuation report.

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- If the IEC has revoked approval/suspended the study, regulatory authorities and Head of the institution must be informed within 14 working days after the full committee meeting.

14.5.3 Notifying the Principal Investigator

- 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.
- In case a letter is sent seeking clarifications/information regarding the premature termination/ suspension/ discontinuation, the PI shall send a written response within 30 days of receiving the letter.
- If the PI does not comply, the matter will be put to the full committee meeting for discussion.
- The investigator may appeal or respond to the convened IEC in writing.

14.5.4 Store the Protocol Documents

- The Secretariat will keep the original version of the Premature Termination Report in the Protocol file and send the file for archival.
- The protocol documents will be stored for a period of 3 years for biomedical and health research from the date of project Termination.

6. Annexure

Annexure 1 AX 01/SOP 14/V1 - Premature Termination Report.

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Annexure 1: AX 01/SOP 14/V1

Premature Termination Report

IEC Protocol no.:			
Protocol title:			
Principal Investigator:			
Department:			
IEC approval date:		Date of last Annual/ Periodic status report submitted to IEC:	
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 IEC? 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 IEC meeting held on _____

Action taken:

Approval of the Premature Termination/ suspension /discontinuation of the project

Requires more information/ action as follows: _____

Signature of Chairperson, IEC with date

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14.7. Flowchart

No.	Activity	Responsibility
1	Receive recommendation for study termination/ suspension / discontinuation	IEC Secretariat
2	Review and Discuss the Termination/ suspension/ discontinuation report	IEC members, Member Secretary and Chairperson
3	Notify the Principal Investigator	IEC Secretariat
4	Store the Protocol Documents	IEC Secretariat