

	Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu	SOP 09/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019
	Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation	



Title: Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation

SOP Code: SOP 09/V5 dated 26th July 2017

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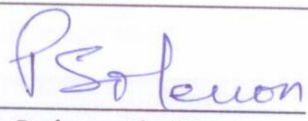
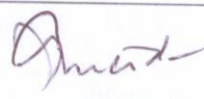

 Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) proceeds and manages the premature termination/ suspension / discontinuation of the study / withdrawal of study before site initiation of a research study. Protocols may be terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

This SOP applies to any study approved by IEC that is being recommended for termination before its scheduled completion.

3. Responsibility

1. It is responsibility of IEC secretariat to receiving premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study report as per (AX 01/SOP 09/V5) submitted by the Principal Investigator and forward it to the member secretary / chairperson with required documents if needed.
2. It is responsibility of the member secretary / chairperson to review the report and take the decision.
3. It is responsibility of the IEC secretariat to record and communicate the decision to the IEC members and PI.

4. Flow chart


No.	Activity	Responsibility
1	Receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study	IEC Secretariat
2	Review the report and take the decision.	Member Secretary / Chairperson
3	To record and communicate the decision to the IEC members and PI.	IEC Secretariat
4	Store the Protocol Documents	IEC Secretariat

5. Detailed instructions

5.1 Receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study.

The Secretariat will receive 1 copy (soft and hard) of premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study filled as per the format – AX 01/SOP 09/V5 from the Principal Investigator.

- It is the responsibility of the IEC Secretariat to review the report for completeness. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.

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- The Secretariat shall forward the premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study Form- AX 01/ SOP 09/V5 and sends it to the Member secretary.

5.2 Review the report and take the decision.

- The member secretary / Chairperson shall review the results, reasons and accrual data and discuss the report at the regular Full Board meeting.
- The Member Secretary in the meeting will inform members of the premature termination of the project and the IEC members will review the Premature Termination Report *AX 01/ SOP 09/V5*
- 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.
- The Chairperson/member secretary / IEC members will review the information available and take a decision depending on the seriousness of the termination. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus / voting.
- This action will be recorded by the Member Secretary.

5.3 Record and communicate the decision to the PI.


The decision will be communicated to the PI within 14 days and Secretariat will record the decision reached on the Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation in the minutes of the meeting.

5.4 Store the protocol documents.

- The Secretariat will keep the original version of the Premature Termination Report *AX 01/ SOP 09/V5* 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

- [1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st July 2017).
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st July 2017)

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7. Annexure

ANNEXURE 1 AX 01/ SOP 09/V5 Premature Termination Report

Annexure 1
AX 01/ SOP 09/V5
Premature Termination Report

IEC Protocol no.:			
Protocol title:			
Principal Investigator:			
Department:			
IEC approval date:		Date of last Annual/ Periodic status report submitted to IEC:	
Starting date:		Termination 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 <input type="checkbox"/> No <input type="checkbox"/>		
Brief summary of results: (use extra blank paper, if more space is required). _____ _____ _____			
Reason/s for termination: _____ _____			