

**Title:** Management of Premature Termination of the study

**SOP Code:** SOP 13/V1 dated 18<sup>th</sup> February 2017

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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 of a research study. Protocols are usually 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**

It is the responsibility of the IEC Chairperson to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the premature termination process.

## **4. Flow chart**

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

## **5. Detailed instructions**

### ***Receipt of recommendation for study termination.***

- The Secretariat will receive recommendation and comments from DSMB, Principal Investigator (PI), Sponsor, Regulator or other authorized bodies for premature termination of study protocol.
- The Secretariat will sign and date the package upon receipt.
- The IEC members/Chairperson can prematurely terminate the study if:
  1. Protocol non-compliance/violation is detected and IEC decision is to terminate the study (SOP 12/V1)
  2. SAE occurring at trial site may require the study to be prematurely terminated for the safety of the patients.
- The Secretariat will inform the Principal Investigator to prepare and submit a Premature Termination Report as per the format AX 01/SOP 13/V1 (available in the IEC office).

- The Secretariat will receive the study protocol termination report (soft and hard copy) and submitted by the Principal Investigator and will check the completeness of the information, including accrual data since the time of the last continuing review.
- The Premature Termination Report *AX 01/SOP 13/V1* signed and dated by the Principal Investigator shall contain a brief written summary of the protocol, its results, and accrual data.

***Reviewing and discussing the Termination Package.***

- The Secretariat will inform the Chairperson regarding the recommendation for premature termination of study protocol and the termination report to the Chairperson within 14 days. The Chairperson shall review the results, reasons and accrual data and either call for an emergency meeting or discuss the report at the regular Full Board meeting.
- The Secretariat will arrange for an Emergency meeting and follow instructions as per SOP 17/V1 or put this in the agenda for the Full Board meeting as per SOP 16/V1
- 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 13/V1*
- The Chairperson shall sign and date the study termination report in acknowledgment and approval of the termination.
- If the Premature Termination Report is unclear or more information is required from the Principal Investigator, the Chairperson shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- If a letter containing comments by the IEC is sent to Principal Investigator, on receipt of the reply letter, it is reviewed as per the steps in 5.2 will be performed by the Secretariat.

***Notifying the Principal Investigator.***

- The Secretariat will make notification letter 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, the principal investigator 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 Secretariat will send the notification letter to the principal investigator within 14 days after the meeting.

***Store the protocol documents.***

- The Secretariat will keep the original version of the Premature Termination Report *AX 01/SOP 13/V1* 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/](http://www.who.int/tdr/publications/publications/) (last accessed 31<sup>st</sup> August 2013).
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31<sup>st</sup> August 2013)

## 7. Annexure

ANNEXURE 1 AX 01/SOP 13/V1 Premature Termination Report

**Annexure 1**  
**AX 01/SOP 13/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:	
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: _____			

Signature with date of Principal Investigator: \_\_\_\_\_

**Discussed at the IEC meeting held on \_\_\_\_\_**

**Action taken:**

Approval of the Premature Termination of the project

Requires more information/ action as follows: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
**Signature with date**  
**Chairperson, IEC**