



# Standard Operating Procedures (SOP -13/01)

For  
**Management of Premature Termination of the  
Study**



## Independent Ethics Committee (Clinical Research) India

### **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe how the Independent 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 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**

<b><u>No.</u></b>	<b><u>Activity</u></b>	<b><u>Responsibility</u></b>
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**

#### ***5.1 Receive recommendation for study termination.***

- The Secretariat will receive recommendation and comments from DSMB, Principal Investigator, Sponsor or other authorized bodies for premature termination of study protocol.



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- 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 12/01)
  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 protocol termination package along with Premature Termination Report *AF/01/01-SOP13/01* (available at IEC office or website [www.iecindia.org](http://www.iecindia.org)).
- The Secretariat will receive the study protocol termination package prepared and submitted by the Principal Investigator and verify the contents of the package for inclusion of:
  - Premature Termination Report (*AF/01/01-SOP13/01*) signed and dated by the Principal Investigator should contain a brief written summary of the protocol, its results, and accrual data.
- The Secretariat will check the completeness of the information, including accrual data since the time of the last continuing review.
- The Secretariat will initial and date the package upon receipt.

### ***5.2 Review and discuss the Termination Package.***

- The Secretariat will notify the Chairperson regarding the recommendation for premature termination of study protocol and send a copy of the termination package to the Chairperson within one working day upon receipt.
- The Chairperson reviews the results, reasons and accrual data and calls for an emergency meeting/regular Full Board meeting (if scheduled within 7 days) to discuss about the recommendation.
- The Secretariat will arrange for an Emergency meeting and follow instructions as per SOP 17/01 (Procedures for conduct of Emergency meeting) or put this in the agenda and organize the Full Board meeting as per SOP 16/01 (Procedures for Agenda Preparation, Meeting Procedures and Recording of Minutes)
- The Secretary in the meeting will inform of the premature termination of the project and the IEC members will review the Premature Termination Report *AF/01/01-SOP13/01*
- The Chairperson signs and dates the study termination report in acknowledgment and approval of the termination.
- If the Premature Termination Report is unclear/more information is required from the Principal Investigator the Secretariat is instructed to send a query letter to the Principal Investigator.



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### ***5.3 Notify the Principal Investigator.***

- The Secretariat will make notification letter acknowledging the approval of termination/query letter to request information regarding the premature termination.
- The Secretariat will send the notification letter to the principal investigator for their records within 10 working days.

### ***5.4 Store the protocol documents.***

- The Secretariat will keep the original version of the Premature Termination Report *AF/01/01-SOP13/01* 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.
- If query letter is sent to Principal Investigator, on receipt of the reply letter, it is reviewed in the forthcoming Full Board meeting and steps in 5.2 will be performed by the Secretariat.

## **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 24 March 2008).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996 - <http://www.ich.org/LOB/media/MEDIA482.pdf>  
(last accessed 24 March 2008)

## **7. Annex**

ANNEX 1      AF/01/01-SOP13/01      Premature Termination Report



**Independent Ethics Committee (Clinical Research) India**

**Annex 1**

AF/01/01-SOP13/01

**Premature Termination Report**

PROTOCOL NUMBER:		IEC PROTOCOL NO.:	
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
TRIAL SITE:			
SPONSOR:			
IEC APPROVAL DATE:		DATE OF LAST PROGRESS REPORT SUBMITTED TO IEC:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS ENROLLED:		NO. OF PARTICIPANTS COMPLETED:	
NO. OF ONGOING PARTICIPANTS:		NO. OF DROP OUTS:	
SAE (TOTAL NO.):	SAE EVENT:		
SUMMARY OF RESULTS:			
REASON FOR TERMINATION:			
P.I.SIGNATURE:		DATE:	



**Independent Ethics Committee (Clinical Research) India**

IEC meeting date: \_\_\_\_\_

Action taken:

**F** Approval of the Premature Termination of the project

**F** Requires more information about the project as follows:

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Chairperson \_\_\_\_\_ Sign/date \_\_\_\_\_