	FERCI MODEL SOPs Management of Premature Termination / Suspension / Discontinuation of the Study	SOP 14/V1: Effective Date: aa/bb/cccc
---	---	---

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

SOP Code: SOP 14/V1

Effective Date: aa/bb/cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

Prepared by:

Dr. PadmajaMarathe, FERIC Member	(Signature with Date)
----------------------------------	-----------------------

Reviewed by:


Dr. U. M. Thatte, FERIC Secretary	(Signature with Date)
Dr. S. K. Kamat, FERIC Treasurer	(Signature with Date)

Approved by:

Dr. VasanthaMuthuswamy, FERIC President	(Signature with Date)
Dr. Nandini Kumar, FERIC Vice President	(Signature with Date)

Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Recommendation for Termination/ Suspension/ Discontinuation	2
4	Detailed Instructions	3
5	References to other applicable SOPs	4
6	Annexures	5
7	Flowchart	6

 <p>FERCI</p>	<p style="text-align: center;"><i>FERCI MODEL SOPs</i></p> <p style="text-align: center;">Management of Premature Termination / Suspension / Discontinuation of the Study</p>	<p style="text-align: center;">SOP 14/V1:</p> <p style="text-align: center;">Effective Date: aa/bb/cccc</p>
---	--	--

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.

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

3. Responsibility

It is the responsibility of the IEC 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 IEC) that the IEC 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 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.

4.2 By IEC

IEC members/Chairperson can prematurely terminate/ suspend/ discontinue the study in

 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Management of Premature Termination / Suspension / Discontinuation of the Study</p>	<p>SOP 14/V1:</p> <p>Effective Date: aa/bb/cccc</p>
---	--	--

the following situations:

- protocol non-compliance/violation following which IEC decides in full board 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.
 - When research is not conducted in accordance with IEC 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.

- The IEC may revoke approval and recommend to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.


5. Detailed instructions

5.1. Receipt of Recommendation for Study Termination.

- The Secretariat will receive the study protocol termination/suspension/discontinuation report submitted by the PI and verify the contents of the report for completeness (AX 01/ SOP 14/V1) and/or other documents (letter from PI / sponsor).

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 the termination/ suspension/ discontinuation report within 3 working days of receipt of the report.
- The Member Secretary/ Chairperson shall review the report 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/ keep matter for discussion at full board meeting as per SOP 07A/V1.

 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Management of Premature Termination / Suspension / Discontinuation of the Study</p>	<p>SOP 14/V1:</p> <p>Effective Date: aa/bb/cccc</p>
---	--	--

- The Member Secretary in the meeting will inform members of the premature termination/ suspension/ discontinuation of the project and the reasons for the same.
- 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 shall sign and date the study termination/ suspension/ discontinuation report in acknowledgement.
- If the IEC 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


- 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 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 IEC 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/V1 - Initial Full-Board Review of Research Study Protocols


 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Management of Premature Termination / Suspension / Discontinuation of the Study</p>	<p>SOP 14/V1:</p> <p>Effective Date: aa/bb/cccc</p>
---	--	--

7. Annexure

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

*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 <input type="checkbox"/> No <input type="checkbox"/>		
Brief summary of results: (use extra blank paper, if more space is required)			

 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Management of Premature Termination / Suspension / Discontinuation of the Study</p>	<p>SOP 14/V1:</p> <p>Effective Date: aa/bb/cccc</p>
---	--	--

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

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