

 <p>FERCI</p>	<p>FERCI MODEL SOPs</p> <p><i>Review of Study Completion Reports</i></p>	<p>SOP 13/V1:</p> <p>Effective Date: aa/bb/cccc</p>
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Title: Review of Study Completion Reports

SOP Code: SOP 13/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]

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report submitted for studies approved by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of the Study Completion Report which is a written report of every completed study submitted by the Principal Investigator (PI).

3. Responsibility

It is the responsibility of the Secretariat/ IEC Chairperson/ Member Secretary/ Member/s to review the study report and act on it.

4. Detailed instructions

4.1. Receipt of Study Completion Report

- The Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – *AX 01/SOP 13/V1* from the PI. The study completion report is expected from the investigator within 1 month of completion of the study at the site.
- The Secretariat will follow instructions as in SOP 06/V1 (Management of Protocol Submission) for receiving and checking the report package.
- It is the responsibility of the IEC Secretariat to review the report for completeness.
- The Secretariat shall verify the submitted Study Completion Report along with Study Completion Report Form- *AX 01/SOP 13/V1* and forward it to the Member Secretary within 7 working days of receipt.
- The Member Secretary will review the Study Completion Report, confirm that it is complete and present it at the next full board meeting.

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- If there is a need felt (e.g. a deviation/ violation is noted), the Member Secretary will handle it as per SOP 11/V1
- The Secretariat shall include the Study Completion Report Form in the agenda for IEC members as per SOP 08/V1 for discussion at the full board meeting.

4.2. During the Board meeting

- The Member Secretary will present the report and members can discuss as needed.
- Following the discussion, the Chairperson may take one of the following decision:
 - a) noted / approved
 - b) request for additional information / clarification
- The Secretariat will note the decision in the meeting minutes
- The Member Secretary will draft a letter to the PI conveying decision on the study completion report.
- The study shall be considered as closed if the decision by IEC is “Noted” or “Approved”.
- The Secretariat will accept and file the Report and get the Study Completion Report Form *AX 01/SOP 13/V1* signed by the Chairperson .
- The final report will be placed in the master file and kept in the archival area.
- The Administrative Officer will archive the entire study for a period of 5 years from the date of completion of the project if the decision is noted and closed.

5. Reference to other applicable SOPs:

- **SOP 06/V1:** *Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review*
- **SOP08/V1:** *Agenda Preparation, Meeting Procedures and Recording of Minutes*
- **SOP11/V1:** *Review of Protocol Deviations / Violations*

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6. Annexures

Annexure 1 AX 01/SOP 13/V1 Study Completion Report

Annexure 1: AX 01/SOP 13/V1

Study Completion Report Form

(Filled by principal Investigator)

IEC Project No.	
Project Title: _____ _____	
Principal Investigator	
Department	
Total no. of study participants recruited	
Total no. of study participants approved by the IEC for recruitment	
Duration of the study	
*Results (summary) with Conclusion: (use extra blank paper, if more space is required). _____ _____	
*Note: If the final report is not available from sponsor, it may be submitted later to the IEC once it is ready.	
Number of SAEs at our center:	
Whether all SAEs intimated to the IEC	Yes <input type="checkbox"/> No <input type="checkbox"/>
No. of patients withdrawn :	
Reasons for Withdrawal of Patients: _____ _____ _____	
Signature of Principal Investigator:	Date :

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<p>Action taken:</p> <p><input type="checkbox"/> Noted</p> <p><input type="checkbox"/> Requires more information/ action as follows:</p> <p>_____</p> <p>_____</p> <p>IEC Meeting date (If reviewed in the meeting) _____</p> <p>Final Decision: _____</p> <p>_____</p> <p>Signature of Member Secretary with date:</p> <p>_____</p>	

7. Flow chart

No.	Activity	Responsibility
1	Receipt of the study completion report	IEC Secretariat
2	Checking the contents of the report packages and assess adequacy of contents	IEC Secretariat
3	Verification of the study completion report, preparation of the study completion statement and sending them to the Member Secretary	IEC Secretariat
4	Review of the Study completion report for completeness and informing members at full-board meeting	Member-Secretary/
5	Inclusion of the report/ review at full-board meeting	IEC Secretariat
6	Discussion and decision at the full board meeting	Member Secretary/ Chairperson
7	Noting the decision in the minutes of the Meeting	IEC Secretariat
8	Conveying decision to the Principal Investigator	IEC Secretariat
9	Archiving all the study-related documents along with the Study completion report	Administrative Officer