	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
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Title: Site Monitoring and Post-Monitoring Activities

SOP Code: SOP 16/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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Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Detailed Instructions	2
5	Annexures	6
6	Flowchart	9

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of an Institutional Ethics Committees (IEC) approved protocol.

2. Scope

This SOP applies to all IEC approved studies for which a routine or for-cause on-site monitoring may be undertaken by the IEC.

3. Responsibility

It is the responsibility of the Full Board or Chairperson and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated IEC member(s) to perform on-site monitoring of selected study site(s).

4. Detailed instructions

4.1. Selection of study sites

- Routine monitoring for a site may be decided at the time of approval of the project by the Full Board.
- This is recorded in the IEC decision form (AX 03/SOP 7A/V1) and in the IEC minutes.
- “*For-cause monitoring*” will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson.
- The reasons for identifying a particular site for “*for-cause monitoring*” could include any one or more of the following:
 - High number of protocol violations,
 - Large number of studies carried out at the study site or by the investigator,
 - Large number of Serious Adverse Events (SAE) reports,

 <p>FERCI</p>	<p>FERCI MODEL SOPs</p> <p>Site Monitoring and Post-Monitoring Activities</p>	<p>SOP 16/V1:</p> <p>Effective Date: aa/bb/cccc</p>
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- High recruitment rate,
- Large number of Protocol deviations,
- Complaints received from participants or any other person,
- Frequent failure to submit the required documents
- Any other cause as decided by IEC.

4.2. Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed
- The Chairperson will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected members will be given an appointment letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson
- The Secretariat will decide the date of the monitoring in consultation with the monitors and the PI.
- The final date will be communicated to the PI (with a request to be available) and monitors.
- The monitor will receive from secretariat and review the relevant project documents and make appropriate notes.
- The Secretariat provided Monitors with relevant reference material / documents related to the project
- Monitors will carry with them Site Monitoring Visit Report Forms- AX 01/SOP 16/V1 and AX 02/SOP 16/V1 (if applicable) collected from the Secretariat.

4.3. During the visit

- The Monitor will follow the check list and:
 - check the log of delegation of responsibilities of study team,

 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Site Monitoring and Post-Monitoring Activities</p>	<p>SOP 16/V1:</p> <p>Effective Date: aa/bb/cccc</p>
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- check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
- observe the informed consent process, if possible,
- review randomly selected participants files to ensure that participants are signing the correct informed consent,
- check investigational product accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study),
- check for storage times, conditions and expiry dates to be acceptable and sufficient supplies available, wherever applicable,
- verify that the investigator follows the approved protocol and all approved amendment(s), if any,
- ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
- verify that the investigator and the investigator's trial staff are performing the specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator/institution, and have not delegated these functions to unauthorized individuals,
- verify that the investigator is enrolling only eligible subjects,
- determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events,
- review the project files of the study to ensure that documentation is filed appropriately,
- review the source documents for their completeness,

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

- collect views of the study participants, if possible,
- The Monitor will fill the Site Monitoring Visit Report Form- AX 01/SOP 16/V1 and AX 02/SOP 16/V1 (if applicable), sign and date it.

4.4. After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form- AX 01/SOP 16/V1 and AX 02/SOP 16/V1 (if applicable) to the IEC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting (whichever is earlier).
- The report should describe the findings of the monitoring visit.
- The Member-Secretary will present the monitoring report at the next full board IEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
 - Continuation of the project with or without changes,
 - Restrictions on enrollment,
 - Recommendations for additional training,
 - Recruiting additional members in the study team,
 - Revising/ providing qualifications/ experience criteria for members of the study team, termination of the study,
 - Suspension of the study, etc.
- If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.

 <p>FERCI</p>	<p align="center">FERCI MODEL SOPs</p> <p align="center">Site Monitoring and Post-Monitoring Activities</p>	<p align="center">SOP 16/V1:</p> <p align="center">Effective Date: aa/bb/cccc</p>
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- The final decision taken at the full board IEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 16/V1*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

5. Reference to other applicable SOPs

SOP 7A/V1 - Initial Full-Board Review of Research Study Protocols

6. Annexures

Annexure 1 *AX 01/SOP 16/V1 - Site Monitoring Visit Report*

Annexure 2 *AX 02/SOP 16/V1 – Monitoring of Audiovisual recording of AV consent Process*

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

Annexure 1: AX 01/SOP 16/V1
Site Monitoring Visit Report
(Please tick the box corresponding to the answer)

IEC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: <input type="checkbox"/> Investigator initiated <input type="checkbox"/> Pharma <input type="checkbox"/> Thesis	
<input type="checkbox"/> Government agency <input type="checkbox"/> Others _____	



FERCI MODEL SOPs
Site Monitoring and Post-Monitoring Activities

SOP 16/V1:
Effective Date: aa/bb/cccc

Date of IEC approval:

Date of Initiation of the study:

Duration of study:

Reason for monitoring: Routine For-cause (State reason/s)
 Protocol Violations/Deviations
 SAE reporting
 Recruitment rate
 Other _____

Last monitoring done, if any,

Yes Date of last monitoring _____
 No

Project Status:


1. Ongoing
2. Completed
3. Recruitment Completed
4. Follow-up, extension study
5. Suspended
6. Terminated

In case of the response to the above question is option 5 or 6, kindly provide reason/s: _____

Recruitment Status: Total patients to be recruited: _____
 Screened: _____
 Screen failures: _____
 Enrolled: _____
 Withdrawn: _____ Reason: _____

 Discontinued: _____ Reason: _____

 Completed: _____
 Active: _____

 <p>FERCI</p>	<p><i>FERCI MODEL SOPs</i></p> <p>Site Monitoring and Post-Monitoring Activities</p>	<p>SOP 16/V1:</p> <p>Effective Date: aa/bb/cccc</p>
---	--	--

<p>Are the present study team members as per the list approved by the IEC</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Are site facilities appropriate?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Is the recent version of Informed Consent Document (ICD), after IEC approval, used?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Whether appropriate vernacular consent has been taken from all patients?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Any other findings noted about the ICDs?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Is recent IEC approved version of protocol used?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Have the eligibility, inclusion exclusion criteria been adhered to? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>
<p>Any adverse events found?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comment:</p>

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

Any SAEs found? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
Were the SAEs informed to IEC within timelines specified by CDSCO? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
No. of deaths reported: <input type="checkbox"/> Deaths unrelated to participation in the trial: <input type="checkbox"/> Deaths possibly related to participation in the trial: <input type="checkbox"/> Deaths related to participation in the trial Any other non-death study related injury	_____ _____ _____ _____ <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA Comments (If Any) _____ _____
Compensation paid for study related injury or death	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
Are all Case Record Forms up to date? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:


	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

Are storage of data and investigating products locked? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
How well are the participants protected? <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Not good	Comment:
Any other remarks <input type="checkbox"/> Yes <input type="checkbox"/> No	Give details:
Duration of visit: _____ hours	Starting from: Finish:
Name of the study team member/s present: Signature _____	Date:
Name of IEC members and representatives who attended monitoring visit:	
Completed by: Signature: _____	Date:

Final Decision at the IEC meeting held on _____

Signature of Chairperson, IEC


with date

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---


Annexure 2: AX 02/SOP 16/V1

Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured):
 - Yes _____ No _____
 - Remarks: _____
2. The consent is taken in language the participant/LAR understands best and is literate in.
 - Yes _____ No _____
 - Remarks: _____
3. Introduction of each person (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) / impartial witness) involved during informed consent process and information about necessity for audiovisual recording
 - Yes _____ No _____
 - Remarks: _____
4. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
 - Yes _____ No _____
 - Remarks: _____
5. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
 - Yes _____ No _____
 - Remarks: _____
6. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.
 - Yes _____ No _____

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
---	--	---

- Remarks: _____
7. Explanation or narration by the person conducting the informed consent discussion.
- Yes _____ No _____
 - Remarks: _____
8. Questions asked by the potential participant/LAR are answered satisfactorily.
- Yes _____ No _____
 - Remarks: _____
9. Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with family members.
- Yes _____ No _____
 - Remarks: _____
10. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement.
- Yes _____ No _____
 - Remarks: _____
11. Documentation of signatures of all those involved in the Informed Consent Process.
- Yes _____ No _____
 - Remarks: _____
12. Clarity and completeness of AV recording
- Yes _____ No _____
 - Remarks: _____
13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team.
- Yes _____ No _____
 - Remarks: _____

	FERCI MODEL SOPs Site Monitoring and Post-Monitoring Activities	SOP 16/V1: Effective Date: aa/bb/cccc
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7. Flow chart

No.	Activity	Responsibility
1	Selection of study sites	IEC Member Secretary / Chairperson
2	Identification of IEC members for monitoring during meeting	Chairperson
2	Inform Principal Investigator in writing	Secretariat
3	Review of IEC protocol file prior to visit and collect Site Monitoring visit report from IEC office	IEC member
4	Review or monitoring of site	IEC member
5.	Complete the monitoring report and present in IEC meeting	IEC member
6.	Communication of IEC decision to PI	Secretariat