Title: Site Monitoring and Post-Monitoring Activities

1. Purpose

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

2. Scope

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

3. Responsibility

It is the responsibility of the Full Board or Chairman and Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated EC 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 EC decision form (AX 03/SOP 7A/V4) and in the EC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the EC, after approval by the Chairman.
- 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,
  - 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 EC.

4.2. Before the visit

- Irrespective of the cause for conducting monitoring the following procedure will be followed
- The Chairman will identify and select one or more EC 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 Chairman
- 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/V4 and AX 02/SOP 16/V4 (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,

- check if the site is using latest EC 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,

- collect views of the study participants, if possible,

- The Monitor will fill the Site Monitoring Visit Report Form- AX 01/SOP 16/V4 and AX 02/SOP 16/V4 (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/V4* and *AX 02/SOP 16/V4* (if applicable) to the EC 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 EC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The EC 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 Chairman and any one of the actions described above will be taken.

- The final decision taken at the full board EC meeting by the Chairman will be recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 16/V4*
- 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/V4 - *Initial Full-Board Review of Research Study Protocols*

6. Annexures

Annexure 1 *AX 01/SOP 16/V4* - Site Monitoring Visit Report

Annexure 2 *AX 02/SOP 16/V4* – Monitoring of Audiovisual recording of AV consent Process

Annexure 1: AX 01/SOP 16/V4

Site Monitoring Visit Report (Please tick the box corresponding to the answer)

EC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Type of study: ☐Investigator initiated ☐Pharma ☐Thesis	
Government agency ☐ Others _____	

Date of EC approval:

Date of Initiation of the study:

Duration of study:

Reason for monitoring: Routing

For-cause (State reasons)
Protocol Violations/Deviations
SAE reporting
Recruitment rate
Others

Last for 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 reasons:

Recruitment Status:

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

Discontinued: Reason:

Completed:

Active:

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

Are the present study team members as per the list approved by the EC Yes No	Comment:
Are site facilities appropriate? Yes No	Comment:
Is the recent version of Informed Consent Document (ICD), after EC approval, used? Yes No	Comment:
Whether appropriate vernacular consent has been taken from all patients? Yes No	Comment:
Any other findings noted about the ICDs? Yes No	Comment:
Is recent EC approved version of protocol used? Yes No	Comment:
Have the eligibility, inclusion exclusion criteria been adhered to? Yes No	Comment:
Any adverse events found? Yes No	Comment:
Any SAEs found? Yes No	Comment:
Were the SAEs informed to EC within timelines specified by CDSCO? Yes No	Comment:

No. of deaths reported: ☐ Deaths unrelated to participation in the trial: ☐ Deaths possibly related to participation in the tri al: ☐ Deaths related to participation in the trial Any other non-death study related injury	_____ _____ _____ _____ Yes No NA Comments (If Any) _____ _____ _
Compensation paid for study related injury or death	☐ Yes ☐ No ☐ NA Comments (If Any)
Are there any protocol non-compliance deviations/violations? Yes No	Comment:
Have the protocol non-compliance deviations/violations been informed to EC? Yes No	Comment:
Are all Case Record Forms up to date? Yes No	Comment:

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

Final Decision at the EC meeting held on _____

_____

_____

Signature of Chairman, EC with date

Annexure 2: AX 02/SOP 16/V4

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 EC.
   - Yes _____ No_____

- 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:_____

7. Flow chart

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

8. References

1. Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 22nd October 2018). Available from: http:// www.ferci.org/sops/
2. Ethical guidelines for biomedical research on human participants. (2017). Indian Council of Medical Research. Available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
3. Ministry of Health and Family Welfare. New Drugs and Clinical Trials Rules, 2019. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

SOP 16	Sri MANAKULA VINAYAGAR Medical college and Hospital	
SOP code: SOP 16/ V4	***Site Monitoring and Post-Monitoring Activities***	**Effective Date: 02.01.2024**

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