Title: Site Monitoring and Post Monitoring Activities

SOP Code: SOP 16/V2
Effective Date: 21-10-2019

SOP Constitution and Approval:

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1. Purpose

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

2. Scope

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

3. Responsibility

It is the responsibility of the Full Board or Chairperson and Member Secretary/Additional Member Secretary to decide to conduct on-site monitoring. It is further the responsibility of the designated IHEC 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 project by Full Board.
- This is recorded in IHEC decision form AX 03/SOP 7A/V2) and in the IHEC minutes.
- *"For-cause monitoring"* will be performed at sites for reasons identified by any member of the IHEC, 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,
  - ➢ 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 IHEC.

4.2. Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed:

- Chairperson will identify and select three IHEC members. IHEC depending on the nature of the study (henceforth referred to as monitors) to conduct monitoring of a site.
- Selected members will be given an appointment letter in this regard.
- Agenda of monitoring will be decided by identified monitors in consultation with Member Secretary/Additional Member Secretary and Chairperson
- Secretariat will decide the date of monitoring in consultation with monitors and PI.
- Final date will be communicated to the PI (with a request to be available) and monitors.
- Monitor will receive from Secretariat and review relevant project documents and make appropriate notes.
- Secretariat will provide Monitors with relevant reference material / documents related to the project
- Monitors will carry with them Site Monitoring Visit Report Forms- AX 01/SOP 16/V2 and AX 02/SOP 16/V2 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 IHEC 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 investigator and investigator's trial staff are adequately informed about the trial,
- verify that investigator and 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/V2 and AX 02/SOP 16/V2, sign and date it.

4.4. After the visit

- The Monitor will submit the completed Site Monitoring Visit Report Form-AX 01/SOP 16/V2 and AX 02/SOP 16/V2 (if applicable) to the IHEC 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/Additional Member Secretary will present the monitoring report at the next full board IHEC meeting and the concerned Monitor will provide additional details/ clarifications to members, as required.
- The IHEC 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 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/Additional Member Secretary on the same day. The Member Secretary/Additional Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.

- The final decision taken at the full board IHEC meeting by the Chairperson will be recorded in the Site Monitoring Visit Report Form AX 01/SOP 16/V2.
- 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/V2 – *Full-Board Review of Research Study Protocols*

6. Glossary

Monitoring visit	An action that IHEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting research, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with prior notification to the principal investigators

7. Annexures

Annexure 1: AX01/SOP016/V2 - Site Monitoring Visit Report

Annexure 2: AX02/SOP016/V2– Monitoring of Audiovisual recording of AV consent Process

Annexure 1: AX 01/SOP 16/V2
Site Monitoring Visit Report

IHEC project no:	Date of Visit:
Study Title:	
Principal Investigator and Department:	
Government agency	Others
Date of IHEC 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: No: Date of last monitoring:
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	
Are the present study team members as per the list approved by the IHEC?	Yes No Comment
Are site facilities appropriate?	Yes No Comment
Is the recent version of Informed Consent Document (ICD), after IHEC 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 IHEC 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 IHEC within timelines specified by CDSCO?	Yes No Comment
No. of deaths reported	Yes No Comment
Any other non-death study related injury	Yes No Comment
Compensation paid for study related injury or death	Yes No Comment
Are there any protocol non compliances, deviations/violations?	Yes No Comment
Have the protocol non-compliance, deviations/violations been informed to IHEC?	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 Fair Comment
Any other remarks	Yes No If Yes, Details
Duration of visit:_____ hours	Started at: Finished at:
Name of the study team member/s present	Signature with date
Name of IHEC members and representatives who attended monitoring visit	
Completed by:	Signature with date

Final Decision at the IHEC meeting held on:
Signature of Chairperson, IHEC with date:

Annexure 2: AX 02/SOP 16/V2
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/ legally acceptable representative (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 IHEC.

   ☐ 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:_____

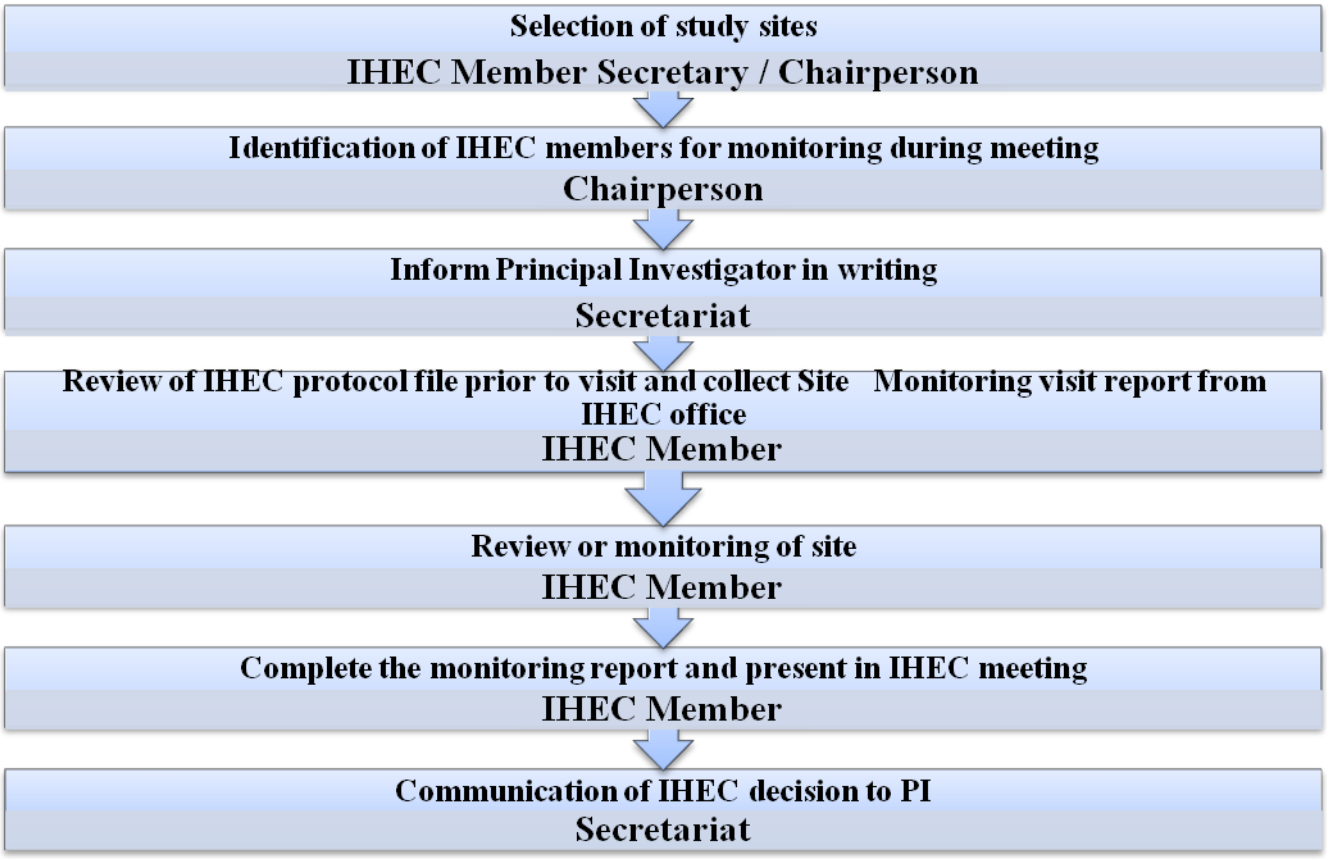
12. Clarity and completeness of AV recording

    - ☐ Yes _____ No_____
    - ☐ Remarks:_____

13. Storage of recording in password protected laptop/ desktop computer and/ or hard drive with access allowed only to the principal investigator and designated members of the study team.

    - ☐ Yes _____ No_____
    - ☐ Remarks:_____

8. Flow chart



9. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: http://www.ferci.org/sops/*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*

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