Title: Site Monitoring Visit
SOP Code: SOP 12/V5.1 dated 2nd April 2018

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select a site for monitoring and how the site will be monitored.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the Institutional Ethics Committee (IEC) approved study protocols.

3. Responsibility

It is the responsibility of the designated IEC member(s) or designated qualified agent to perform on-site inspection of selected study site(s) of relevant projects it has approved.

The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites and Identification of monitors for site monitoring	IEC members / Chairperson
2	Before the visit	IEC members / representative, Secretariat
3	During the visit	IEC members / representative
4	After the visit	IEC members /representative, Secretariat

5. Detailed instructions

5.1 Selection of study sites and Identification of monitors for site monitoring

- IEC will identify the site(s) for routine monitoring at the time of approval of the project depending upon the reason provided by any IEC member or later after the start of the project can be for cause monitoring . This decision will be recorded in the IEC Decision Form - *AX 01/SOP 05-A/V5.1*.
- The Chairperson will identify and designate one or more IEC members or independent monitor to carry out routine monitoring of the study site.
- The reason for identifying a particular site for 'monitoring' will be provided to an IEC member. This cause could include any one or more of the following:
  - Routine monitoring
  - High number of protocol violations, or
  - Large number of studies carried out at the study site or by the investigator, or
  - Remarkable number of SAE reports, or

- High recruitment rate, or
- Non-compliance, or
- Suspicious conduct, or
- Complaints received from participants, or
- Any other cause as decided by IEC.

- After discussion at an IEC meeting, decision regarding conducting 'monitoring' will be taken. The Chairperson will identify and select one or more IEC members or independent monitor who along with IEC members will conduct monitoring of a site.

5.2 Before the visit

- The IEC Chairperson will designate an IEC member or appoint an Independent monitor who along with IEC members will perform the task of monitoring. The selected member or independent monitor will be provided with an appointment letter in this regard. A copy of the appointment letter along with the agenda for monitoring (mentioned in SOP 12 Version 5.1 point no. 5.3) will be forwarded to the Principal Investigator of the site to be monitored. The IEC members and independent monitor (if designated) will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.
- The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit.
- The IEC member(s)/ Independent monitor along with IEC members will:
  - contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.
  - review the IEC project files for the study and site profile and make appropriate notes.
  - be provided with relevant reference material/ documents related to the project that may have to be referred to during the study visits and collect the Site Monitoring Visit Report Form- AX 01/SOP 12/V5.1 from the Secretariat.

5.3 During the visit

- The IEC member/Independent monitor along with IEC members will-
  - ✓ Check the log of delegation of responsibilities of study team
  - ✓ Check if the site is using latest IEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
  - ✓ Review the informed consent document to make sure that the site is using the most recent version,
  - ✓ Observe the informed consent process or audio visual consent or audio consent , if possible,

- ✓ Review randomly selected participants files to ensure that participants are signing the correct informed consent,
- ✓ Observe laboratory and other facilities necessary for the study at the site, if possible.
- ✓ 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.
- ✓ Fill the Site Monitoring Visit Report Form- *AX 01/SOP 12/V5.1*, sign and date it.

5.4 After the visit

- The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 12/V5.1 to* the IEC secretariat within *14 days* of conducting a site monitoring visit.
- 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 IEC member/ independent 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.
- The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 12/V5.1*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

6. Glossary

Independent monitor	The expert with appropriate experience and training, who is not an IEC member, who may or may not be affiliated to the institution and who will perform the tasks of site monitoring along with designed IEC members.
Monitoring visit	An action that IEC 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. References

[1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (last accessed 31st July 2017).

[2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed 31st July 2017).

[3] Audio video recording of informed consent process in clinical trial , Drugs and cosmetics (second amendment)Rules 2013http://cdsco.nic.in/writereaddata/GSR%20364Ejune13.pdf (last accessed 31st July 2017).

[4] DCGI Draft Guidelines on Audio-visual recording of Informed Consent Process dated 16th January 2014 - http://cdsco.nic.in/forms/list.aspx?lid=2057&Id=31 (last accessed 19th October 2016)

[5]. FERCI Draft Template: SOP for AV Recording of Informed Consent Process: http://ferci.com/wp-content/uploads/2014/01/AV-Consent-FERCI-template_06_01_14-Final-1.doc (last accessed 19th October 2016)

8. Annexure

Annexure 1	*AX 01/SOP 12/V5.1*	Site Monitoring Visit Report
Annexure 2	*AX 02/SOP 12/V5.1*	Checklist for Monitoring of Audiovisual recording of AV consent Process
Annexure 3	*AX 03/SOP 12/V5.1*	Guidance document for audiovisual recording of AV consent Process

Annexure 1

AX 01/SOP 12/V5.1

Site Monitoring Visit Report

IEC project no.	Date of the Visit:
Study Title:	
Principal Investigators:	
Department:	
Total number of participants enrolled:	Total participants ongoing:
No. of participants completed:	No. of drop outs including reasons:
Are the present study team members as per the list approved by the IEC ☐ Yes ☐ No	Comment:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Is recent version of Informed Consent Document (ICD) used? ☐ Yes ☐ No	Comment:
Is it approved by the IEC? ☐ Yes ☐ No	Comment:
Whether consent has been taken from all patients? ☐ Yes ☐ No	Comment:
Whether appropriate vernacular consent has been used? ☐ Yes ☐ No	Comment:
Any other findings noted about the ICDs ☐ Yes ☐ No	Comment:
Is recent version of protocol used? ☐ Yes ☐ No	Comment:
Is it approved by the IEC? ☐ Yes ☐ No	Comment:

Any adverse events found? ☐ Yes ☐ No	Comment:
Any SAEs found? ☐ Yes ☐ No	Comment:
Were the SAEs informed to IEC within the timelines ? ☐ Yes ☐ No	Comment:
Any there any protocol non-compliance deviations/violations? ☐ Yes ☐ No	Comment:
Have the protocol non-compliance deviations/violations been informed to IEC ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are all the source documents available ☐ Yes ☐ No	Comment:
Are all the data transferred from source documents to CRF appropriate ☐ Yes ☐ No	Comment:
Are there a equitable selection of participants ☐ Yes ☐ No	Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
Are any of the participants interviewed Yes No	Comment :
How was the participant understanding about the informed consent process	Comment :
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit:_____hours	Starting from: Finish:

Additional comments with summary:	
Name of IEC members and representatives who attended the monitoring visit:	
Completed by: Signature:_____	Date:

Final Decision at the IEC meeting held on _____

_____

Signature with date
Chairperson, IEC

Annexure 2

AX 02/SOP 12/V5.1

Checklist for 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, dedicated room , camera permanently set /temporary arrangement, voice recording to be tested before hand):
    a. Yes _____ No_____
    b. Remarks:_____

2. Whether consent for AV recording already taken before start of recording/ it is taken in front of the camera Yes _____ No _____

3. Whether elements enlisted in Appendix V of Schedule Y is covered during discussion.
    a. Yes _____ No_____
    b. Remarks:_____

4. Introduction of each person – name , age (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) wherever relevant / impartial witness wherever relevant) involved during informed consent process and information about necessity for audiovisual recording - by name, designation and his/ her role in the research, current date and time, enquiry of the language participant understands , showing the consent form in the camera which is going to be used for the study
    a. Yes _____ No_____
    b. Remarks:_____

5. The following minimum elements should feature in the recording of the informed consent process: (Purpose , treatment allotment ,randomization , procedure , follow up , benefit/risks, compensation for Participation, Compensation for Study related Injury, nominee name and details , voluntariness and right to withdraw and contact for further information – Investigator name and EC Chair/member secretary name)
    a. Yes _____ No_____
    b. Remarks:_____

6. If IC has been administered by a designated person who is not medically qualified?
    a. Yes _____ No_____
    b. Remarks:_____

7. Is there evidence that subject's queries of a medical nature were answered in the process or assurance was given to clarify the same later ?

a. Yes _____ No_____
b. Remarks:_____

8. The consent is taken in language the participant/ legally acceptable representative (LAR) understands best and is literate in.
   a. Yes _____ No_____
   b. Remarks:_____

9. 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.
   a. Yes _____ No_____
   b. Remarks:_____

10. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
    a. Yes _____ No_____
    b. Remarks:_____

11. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.
    a. Yes _____ No_____
    b. Remarks:_____

12. Explanation or narration by the person conducting the informed consent discussion.
    a. Yes _____ No_____
    b. Remarks:_____

13. Whether audio-visual recording is performed for all subjects, independently.
    a. Yes _____ No_____
    b. Remarks:_____

14. Questions regarding participation asked by the potential participant/LAR are answered satisfactorily.
    a. Yes _____ No_____
    b. Remarks:_____

15. Ample time was given to read and understand the consent as per the content?
    a. Yes _____ No_____
    b. Remarks:_____
16. Opportunity to discuss the same with family members
    a. Yes _____ No_____
    b. Remarks:_____

17. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent
    a. Yes _____ No_____
    b. Remarks:_____

18. Stating whether participant agrees or not for each statement.
    a. Yes _____ No_____
    b. Remarks:_____

19. Whether checked for participants understanding of the informed consent process
    a. Yes _____ No_____
    Remarks:_____

20. Documentation of signatures of all those involved in the Informed Consent Process.
    a. Yes _____ No_____
    b. Remarks:_____

21. Clarity and completeness of AV recording (pages vis-a- vis timing)
    a. Yes _____ No_____
    b. Remarks:_____

22. Check whether re-consenting is done for changes in ICF/LAR inclusion in the beginning if any.
    a. Yes _____ No_____
    b. Remarks:_____

23. Check whether re-consenting is done by the same Investigator
    a. Yes _____ No_____
    b. Remarks:_____
24. Whether re-consenting is done in same language
    a. Yes _____ No_____
    b. Remarks:_____

25. How much timing taken for the re-consent
    a. Yes _____ No_____
    b. Remarks:_____

26. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD
    a. Yes _____ No_____
    Remarks:_____

27. Access of AV consent recorded allowed only to the principal investigator and designated members of the study team.

a. Yes _____ No_____
Remarks:_____

Signature and date of PI /Co-inv _____

Annexure 3

AX 03/SOP 12/V5.1

Guidance document for audiovisual recording of AV consent Process

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording. YES /NO
3. All parties are reminded that this AV recording is in compliance with regulatory requirements YES /NO
4. All parties are informed that this AV recording will be kept confidential but can be shown to others as per legal requirements or for ensuring compliance with law. YES /NO

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. The member of the research team should state the date, time, title of the research protocol and the language of the written informed consent document. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. If translator is involved, he/she should confirm that he/she is proficient in the language of the informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process. YES /NO
6. At any point during the recording, any participant may request for a break (eg to go to the bathroom or answer a phone). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO

2. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO

3. Rename the file with the unique number for the patient on this research protocol. YES /NO

4. Make backup one by copying that file onto the dedicated external HDD that shall be used to document all consent AV recording for a specific research protocol. YES /NO

5. This external HDD should be suitably labeled and password protected. YES /NO

6. Store the external HDD in a secure location to ensure confidentiality. YES /NO

7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO

8. This should also be suitably located, labeled and password protected. YES /NO