Annexure- 26 A

Site Monitoring Visit Report

(Please tick the box corresponding to the answer)

IEC project no.	Date of Visit:
Study Title:	
Principal Investigator and Department: □For	
Type of study: □Investigator initiated □Pharma □Thesis	
Government agency Others _____	
Date of IEC approval: Date of Initiation of the study: Duration of study:	
Reason for monitoring: □ Routine □ -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: _____	

□ Completed: _____ : □ Active: _____ □ Screened: _____ □ Screen failures: _____ □ Enrolled: _____ □ Withdrawn: _____ Reason: _____ _____ □ Discontinued: _____ Reason: _____ _____	
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 the recent version of Informed Consent Document (ICD), after IEC 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 IEC 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 IEC within timelines specified by CDSCO? ☐ Yes ☐ No	Comment:
No. of deaths reported: □ Deaths unrelated to participation in the trial: al: □ Deaths related to participation in the trial Any other non-death study related injury □ Deaths possibly related to participation in the tri	_____ _____ _____ _____ ☐ 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 IEC? ☐ 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 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

Annexure 26 B

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_____

- 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 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:_____