Annexure 1

AX 01/SOP 25/ V 7

Checklist for Monitoring of Audiovisual recording of AV consent Process

IEC No. of the Project: ……

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 NDCTR 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 Inclusion Criteria 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 the 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 ……..
b. 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 ……..
    b. Remarks ……
27. Access of AV consent recorded allowed only to the principal investigator and designated members of the study team.
    a. Yes …… No ……..
    b. Remarks ……

Signature of IEC Monitors:

Signature of IEC Monitors		
	Name	**Signature with date**
Lead monitor		
Monitor 1		
Monitor 2		
IEC Admin 1		
IEC Admin 2		