Annexure 2

AX 02/SOP 12/V5

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 _____