Annexure 2
AX 02/SOP 12/V6.1

Checklist for Monitoring of Audiovisual recording of AV consent Process

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. .....

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_____
    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 and date of PI /Co-inv _____