



INSTITUTIONAL ETHICS COMMITTEE (IEC)
Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 1

AX 01/SOP 25/ V 7.1

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.



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- 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



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- 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		