Title:	Audio Visual (AV) Recording of Informed Consent Process.
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Prepared by **Signature with date**	Reviewed by **Signature with date**	Approved by **Signature with date**	**Accepted by**
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1. Purpose

The purpose of this SOP is to describe the procedures for Audio-Visual (AV) recording, storage and archival of the informed consent and assent process for regulatory studies.

2. Scope

This SOP applies to all those regulatory clinical trials approved by the DCGI, which require documenting of the written informed consent and assent process.

2.1 An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record:

2.2 Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

2.3 Statement that there is a possibility of failure of IP to provide intended therapeutic effect

2.4 Statement that in case of Placebo controlled trials, the placebo administered to thesubjects shall not have any therapeutic effect

2.5 Any other pertinent information

3. Responsibility

1. IEC will ensure that Principal investigator will conduct AV recording of the informedconsent process, store and archive without violating the participant confidentiality as detailed below in section 6.
2. IEC will specifically ask for consent for AV Consenting in addition to the ICF
3. AV recordings may be reviewed periodically by IEC members

4. Applicable rules, regulations and guidelines:

GSR 227-E, New Drugs and Clinical Trials Rules, 2019 published in the Gazette of India dated 19th March 2019.

5. Detailed Instructions for PI to follow:

All basic principles and procedures for the administration and documentation of the informed consent process are described in SOP Initial review of submitted protocol.

1) If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally acceptable representative (LAR) and the process recorded.
2) If the participant/LAR is illiterate, then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.
3) AV recording should be done with assent wherever applicable.
4) Ensure the following infrastructure is available prior to counseling of potential participant:
   a. The informed consent process should be carried out in the designated area when the following conditions should be met) that is -
      i. Free from disturbance
      ii. Well lit
      iii. Ensures privacy for the participant
      iv. Participant should be comfortable
   b. Camera having video facility with
      ✓ Good resolution (at least1280x720 pixels)

- ✓ Sufficient memory (at least 4 GB)
- ✓ Sufficient battery backup (at least 2 hours)
- ✓ Show non-editable date & time on video (preferably)
    a. Mike system
    b. Computer/laptop with CD/DVD writer
    c. Blank CDs/DVDs with cover
    d. External Hard disk (at least 500 GB to 1 TB)

5) Before starting the informed consent process (and the AV recording of the same)

i. Ensure that all the necessary equipment mentioned above is functional.
ii. The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that he/she has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and his/her rights for the purpose of documentation and the confidentiality of the same is assured.
iii. The potential participant/LAR/ impartial witness should be made aware that his/her recording may be shown to government agencies or members from the IEC and independent auditors.
iv. His/her consent should be documented in a separate ICD that states the same. The process of obtaining signatures of the potential participant/LAR/ impartial witness & Principal Investigator or her designee on this Audio-video consent form should be carried out as per specified in Annexure AF/IEC/04/08/V-8.0 of SOP/08/V-8.0.

6. Actual AV recording process:

i. The PI/Co-I/medically qualified person delegated by the PI and the potential participant/LAR (and if need be the impartial witness) should sit comfortably facing each other / side-by-side in such a way that their faces will be captured in the frame simultaneously.
ii. The PI/Co-I/medically qualified person delegated by the PI should introducehimself/herself by name, designation and his/ her role in the research, and state the current date and time.
iii. Participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language he/she understands best and is literate in. The PI/Co-I/medically qualified person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.
iv. In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce him/her, give his/her address and state the language that he/she is literate in.
v. The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for the same.
vi. The Informed Consent Process should be carried out as per SOP 08/V-8.0:Administering and documenting informed consent.
vii. The participant should be allowed to read the consent document (and this processshould be recorded)
viii. The PI/Co-I/medically qualified person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potential participant
ix. Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible and recorded.
x. At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives

the recording shall be stopped mentioning the time of stopping.

xi. The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above-mentioned questions.

xii. Participant/LAR should read out all the statements mentioned in ICF as per Schedule-Y and state whether he/she agrees or not for each statement and affix signature/thumb print at the end

xiii. The actual signing process should be recorded.

xiv. The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.

xv. The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of the process.

xvi. The recording will be stopped after thanking the participant.

- The recording should be checked for completeness and clarity of both audio and video recording.
- No editing should be done on the recording so as to maintain authenticity.
- The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI. A register should be maintained wherein, each time the data is accessed, the details of who accessed thedata, date and reasons for the same this should be entered into the designated register.
- The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting) and archived in the external Hard drive. The CD should be filed in the participant binder.
- The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect.
- In case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

7. Archival

a. The soft copies of the recordings should be stored in a password protected external hard drive for minimum of five years.

b. The original recording in the computer/laptop will be deleted when study is closedout.

8. Annexure

Annexure 1, *AX 01/SOP 25/* V1, Checklist for Monitoring of Audiovisual recording of AV consent Process

Annexure 2, *AX 03/SOP 25/* V1, Guidance document for audio visual recording of AV consent process

Annexure 1
AX 02/SOP 25/ V1

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 betested before hand):
   a. Yes_____No_____
   b. Remarks: _____

(Audio Visual (AV) Recording of Informed Consent Process)

2. Whether consent for AV recording already taken before start of recording/ it is taken in front of thecamera 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 beused 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 orassurance 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 ofinformation 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 beshown 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 statementsmentioned 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_____

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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 andlabelled CD
    a. Yes_____No_____ Remarks: _____

27. Access of AV consent recorded allowed only to the principal investigator and designated membersof the study team.
    a. Yes_____No_____ Remarks: _____

Signature and date of PI /Co-inv _____

Annexure 2
AX 03/SOP 25/V1

Guidance document for audiovisual recording of AV consent Process

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording. YES /NO
3. All parties are reminded that this AV recording is in compliance with regulatory requirements YES /NO
4. All parties are informed that this AV recording will be kept confidential but can be shown to others as per legal requirements or for ensuring compliance with law. YES /NO

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. The member of the research team should state the date, time, title of the research protocol and thelanguage of the written informed consent document. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. If translator is involved, he/she should confirm that he/she is proficient in the language of the

informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process. YES /NO

6. At any point during the recording, any participant may request for a break (*e.g.* to go to the bathroom or answer a phone or if mother want to feed her baby). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
2. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
3. Rename the file with the unique number for the patient on this research protocol. YES /NO
4. Make backup one by copying that file onto the dedicated external Hard Disk which will be used todocument all consent AV recording for a specific research protocol. YES /NO
5. This external HDD should be suitably labeled and password protected. YES /NO
6. Store the external HDD in a secure location to ensure confidentiality. YES /NO
7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO
8. This should also be suitably located, labeled and password protected. YES /NO