# Draft Template - SOP for Audio Visual Recording of Informed Consent Process

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1. **Background**

As per the DCGI office order dated 19th November 2013, Audio Visual (AV) recording of the informed consent process has been made mandatory for regulatory clinical trials following the Supreme Court order dated 21st Oct 2013. The main idea & purpose behind AV recording of the consent process is to ensure and document that the clinical trial participants are adequately informed about all aspects of the clinical trial including risks and benefits and chances of failure of the Investigational Medicinal Product (IMP) to give intended therapeutic effect and to ensure that they have understood the details of the study including their right so that individual’s voluntary participation is ensured and document that this is done.

2. **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.

3. **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.

4. **Responsibilities**

Principal investigator, Co-Investigator or any other medically qualified member of staff in the team, as delegated by the Principal Investigator, who have the responsibility of obtaining an informed consent, will also be responsible for ensuring AV recording of the informed consent process, storing and archiving without violating the participant confidentiality.
5. **Applicable rules, regulations and guidelines**


6. **Detailed Instructions**

All basic principles and procedures for the administration and documentation of the informed consent process will be applicable besides those mentioned below

1. AV recording of the entire informed consent process is mandatory for all clinical trials approved by the DCGI and consent for the same should be taken.
2. AV recording for any re-consenting procedure that may follow must be done.
3. **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.**
4. **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.**
5. AV recording should be done of assent process wherever applicable.
6. Separate recordings one for assent and one for consent process should be done.
7. 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 (unless patient is on a bed) 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 least 1280x720 pixels)
      ✓ Sufficient memory (at least 4 GB)
      ✓ Sufficient battery back up (at least 2 hours)
      ✓ Show non editable date & time on video (preferably)
   c. Mike system
   d. Computer with CD/DVD writer
   e. Blank CDs/DVDs with cover
   f. External Hard disk (at least 1 TB)

8. Participant should be made comfortable first before starting the informed consent process.

9. Before starting the informed consent process (and the AV recording of the same)
   a. Consent for AV recording should be taken from the participant/LAR.
   b. Ensure that all the necessary equipments mentioned above are functional.
   c. 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 she/he has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and her/his rights for the purpose of documentation and the confidentiality of the same is assured.
   d. The potential participant/LAR/ impartial witness should be made aware that her/his recording may be shown to government agencies or members from the IEC.
10. Actual AV recording process

- 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.
- The PI/Co-I/medically qualified person delegated by the PI should introduce herself/himself by name, designation and her/ his role in the research, and state the current date and time. Mention the title of the protocol and screening number of the participant.
- Participant/LAR should be requested to introduce her/his name, age and address and in case of LAR, she/he 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 she/he 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.
- In case participant/LAR is illiterate then an impartial witness is needed, the impartial witness should be requested to introduce herself /himself, give her/his address and state the language that she/he is literate in.

**The participant should be allowed to read the consent document (and this process should be recorded)**
- 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.
- 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.
- 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. When she/he returns, the recording from the point where it was
stopped before shall be resumed as mentioned before stating clearly again the date and time of recording.

- If the potential participant/ LAR (wherever applicable) agrees to participate in the trial, she/he should be asked questions to assess her/his understanding of the informed consent process. *(Please refer to Appendix 1- Informed consent process assessment tool)*
  - The participant/LAR (wherever applicable) should be invited to sign (or attest left hand thumb impression) the consent form only after satisfactory answers (in the investigator’s judgment) have been given by the participant/ LAR to all the above mentioned questions.
  - Participant/LAR should read out all the statements mentioned in ICF and state whether she/he agrees or not for each statement and affix signature/thumb print at the end
  - The actual signing process (or attesting left hand thumb impression) should be recorded.
  - 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.
  - 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.
  - The recording will be stopped after thanking the participant.

11. The recording should be checked the by PI/Co-I/medically qualified person delegated by the PI for completeness and clarity of both audio and video recording using a dedicated laptop (site’s own / provided by the sponsor) in which the original recording will be stored.
12. No editing should be done on the recording so as to maintain authenticity.
13. The 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. Each time the laptop is accessed; this should be entered into the designated register.
14. 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 an external hard drive.
hard drive will remain with the PI which could be accessed by the delegated study team members on request for transferring and storage The CD should be filed in the participant binder.

15. Archival

a. One CD per participant will be archived with appropriate labeling in participant binder.

b. The soft copies of the recordings will also be stored in a password protected hard drive.

c. The original recording in the laptop will be deleted when study is closed out.

7. Appendices

Appendix 1

Informed consent process assessment tool
Appendix 1

Tool to assess understanding of informed consent document by participant

1. Do you understand that this is research?

2. Is the purpose of the research clear to you?

3. Will you get the treatment which the doctor thinks is best for you?

4. What are the potential risks involved in this study?

5. What are the potential benefits of participating in this study?

6. Have you understood that you will receive_____ amount in consideration for your participation (if normal volunteer) or in consideration for your travel expenses (if patient)?

7. Do you understand that participation in this research is voluntary?

8. Have you understood that you may receive either the test medicine or the active comparator – a drug used in therapy currently or placebo?

9. Have you understood what you should do if you suffer any untoward event?

10. Do you understand that you can withdraw from the research at any time without giving a reason and without it affecting your regular care?

11. Do you know whom to contact if any questions regarding this clinical trial?

12. Do you know whom to contact in emergency or if any injury occurs during your participation in this clinical trial?
13. Have you understood that if you suffer any serious injury during your participation, you will get free medical treatment and will be compensated for this injury if it is related to the trial?

14. Has anybody forced, induced, influenced, allured or pressurized you to agree to participate in the clinical trial?

15. Do you understand that none of your legal rights will be waived by participating in this research?

16. Have you understood the study procedures explained to you? (number of study visits, number of times blood or any biological sample donation, amount of blood draw per visit etc.)

17. Have all your questions about the research been answered?

18. Have you understood that your information about participation and also video recording will be kept confidential?

* This is a model questionnaire which can change according to protocol and ICD.