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

SOP Code: SOP/10/V1.1

Effective date : 04/03/2016

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1. Background

As per the DCGI office order dated 19thNovember 2013, Audio Visual (AV) recording of the informed consent process was made mandatory for regulatory clinical trials. This office order is in support to order dated 21st Oct 2013 from the Honorable Supreme Court of India. The main idea & purpose behind AV recording of the consent process is to ensure 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.

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.

1. **AV recording of the entire informed consent process is mandatory for all clinical trials approved by the DCGI, provided that they come under the following categories.**
2. **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 providing information to the subject and his understanding of such consent, shall be maintained by the investigator for record.**

   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.

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

- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. GCT/ 20/SC/Clin./2013 DCGI dated 19th November 2013
- Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. X.11014/1/ 2012 - DFQC dated 31st July 2015
- Schedule Y (Jan 2005)
- Ethical Guidelines for Biomedical Research on Human Participants, ICMR 2006
- International Conference on Harmonization; Good Clinical Practice Guidelines: May 1996
- Indian GCP 2001

6. Detailed Instructions

All basic principles and procedures for the administration and documentation of the informed consent process (as described in SOP Initial review of submitted protocol SOP/08/V1.5)

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 wherever applicable
6. 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 back up (at least 2 hours)
      - ✓ Show non-editable date & time on video (preferably)

      c. Mike system
      d. Computer/laptop with CD/DVD writer
      e. Blank CDs/DVDs with cover
      f. External Hard disk (at least 500 GB to 1 TB)
7. Before starting the informed consent process (and the AV recording of the same)
   - Ensure that all the necessary equipment mentioned above is functional.
   - 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.
   - 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.
   - 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/EC/04/08/V1.5 of SOP/08/V1.5
8. 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 himself/herself by name, designation and his/ her role in the research, and state the current date and time.
- 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.
- In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce himself/herself, give his/her address and state the language that he/she is literate in.
- 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.
- The Informed Consent Process should be carried out as per SOP 08/V1.5: Administering and documenting informed consent.
- 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 he/she 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.
- 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.
- 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
- The actual signing process 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.

9. The recording should be checked for completeness and clarity of both audio and video recording.
10. No editing should be done on the recording so as to maintain authenticity.
11. 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 the data, date and reasons for the same this should be entered into the designated register.
12. 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.
13. The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect.
14. In case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.
15. Archival
    a. The CDs will be archived with each participant binder as per SOP/22/V1.0 Archival and retrieval of documents
    b. The soft copies of the recordings will also be stored in a password protected external hard drive.
    c. The original recording in the computer/laptop will be deleted when study is closed out.

7. References:

1. Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), F.No. GCT/ 20/SC/Clin./2013 DCGI dated 19th November 2013.
2. Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), Gazette of Indian New Delhi, dated 31st July 2015 No.489.
3. Draft Guidelines on Audio-Visual Recording of Informed Consent Process in Clinical Trial, CDSCO, MOHFW, 9th Jan 2014.
4. FERCAP guidelines for Audio-Visual consent process.

ANNEX 1 **AF/EC/1/10/V1.1**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	4th March 2016	• Addition of the sentence under the bullet 6 2nd point: 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 providing information to the subject and his understanding of such consent, shall be maintained by the investigator for record. 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. • Addition of the sentence under the bullet 6 as point no.13 "The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect" and point no.14 "In case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect". • Version of SOP 8 changed to V1.5 wherever applicable