Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

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

SOP Code: 08/V1.4 Dated:8th November 2024 Page Nos: 138 to 147

Consent process:

As per the DCGI office order dated 31st July 2015, Audio-visual (AV) recording of the informed consent process was made mandatory for regulatory clinical trials. This office order follows the order dated 21st Oct 2013 from the Honorable Supreme Court of India 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 the 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.

As per the NDCT Rule 2019, dated 19th March 2019, an audio-video recording of the informed consent process in case of vulnerable participants in clinical trials of a New Chemical Entity or New Molecular Entity including procedure of providing information to the participant and his/her understanding on such consent, shall be maintained by the investigator for record.

8.1 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.

8.2 Scope

This SOP applies to all those regulatory clinical trials, approved by the DCGI, which require documentation 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 participants in clinical trials of New Chemical Entity or New Molecular Entity including procedure providing information to the participant 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 participant including the procedure of providing information to the participant and his understanding on such consent shall be maintained by the investigator for record.

8.3 Responsibilities

Principal investigator, Co-Investigator or any other suitably qualified any other trained member from the 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.

8.4 Applicable rules, regulations, and guidelines

a. 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
b. 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
c. New Drugs Clinical Trials Rules in 2019
d. International Conference on Harmonization; Good Clinical Practice Guidelines: May 1996 (R1)
e. Indian GCP 2001
f. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

8.5 Detailed Instructions

All basic principles and procedures for the administration and documentation of the informed consent process (as described in SOP Templates for protocol & other submissions SOP/06/V2.0)

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 of 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
      i Good resolution (at least 1280x720 pixels)
      ii Sufficient memory (at least 4 GB)
      iii Sufficient battery backup (at least 2 hours)
      iv 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)

5. Before starting the informed consent process (and the AV recording of the same)
   a. Ensure that all the necessary equipment mentioned above is functional.
   b. 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, study details and his/her rights for the purpose of documentation and the confidentiality of the same is assured.

c. The potential participant/LAR should be made aware that her/his recording may be shown to government agencies or members from the IEC and independent auditors.
d. Her/his consent should be documented in a separate ICD that states the same.
e. 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.

6. Actual AV recording process
   a. The PI/Co-I/ suitably 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.
   b. 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.
   c. 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/person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.
   d. In case participant/LAR is illiterate and 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.
   e. The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that she/he has agreed for the same.
   f. The Informed Consent Process should be carried out as per SOP 06/V2.0: Administering and documenting informed consent.
   g. The participant should be allowed to read the consent document or PI/person delegated by PI reads it out to her/him and this process should be recorded.
   h. The PI/Co-I/person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potential participant
   i. Explanation or narration given by the PI/Co-I/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.
   j. 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.

k. 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.
l. Participant/LAR should read out all the statements mentioned in ICF as per NDCT Rules, 2019 and state whether she/he agrees or not to each statement and affix signature/thumb print at the end
m. The actual signing process should be recorded.
n. 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.
o. The PI/Co-I/ person delegated by the PI will also sign and date the consent form at the end of the process.
p. The recording will be stopped after thanking the participant.

7. The recording should be checked for completeness and clarity of both audio and video recording.
8. No editing should be done on the recording so as to maintain authenticity.
9. 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 register concerned.
10. 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.
11. The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect.
12. In case of placebo-controlled trial, the participants should be told that they could possibly be included in the placebo arm and that placebo has no therapeutic effect.
13. Archival
    a. The CDs will be archived with each participant binder as per SOP/24/V1.2 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.

8.6 ANNEX

Annex 1 Checklist for Monitoring of Audiovisual recording of AV consent Process

Annex 2 Document History

ANNEX 1 **AF/01/08/V1.4**

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 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 as per provisions according to NDCT 2019 rules 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: (Statement that this is for research/ Purpose, treatment allotment, randomization, procedure, follow up, benefit/risks, Confidentiality, reimbursement/ 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 participant'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 participants, 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 participant's 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-investigator: _____

ANNEX 2 **AF/02/08/V1.4**

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	24th September 2014	Final approved copy
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 participants in clinical trials of New Chemical Entity or New Molecular Entity including procedure providing information to the participant 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 participant including the procedure of providing information to the participant 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 participants shall not have any therapeutic effect". ● Version of SOP 8 changed to V1.5 wherever applicable
Dr. Ragini Kulkarni	Version 1.2	7th November 2017	● Date corrected for DCGI office order from 19th November 2013 to 31st July 2015 in the first paragraph. ● Recent ICMR 2017 Guidelines were added to point no. 5 & point no. 7 ● Added Annex 2, 'Checklist for ….. AV consent Process'
Dr. Beena Joshi	Version 1.3	1st May 2019	● SOP no. changed from 10 to 8 ● Document History changed as Annex 2
Dr. Vikrant Bhor	Version 1.4	8th November 2024	All bullets are numbered. ● 8.5 (5b) including failure of the IMP is deleted ● Annex 1 Point 3 Appendix V of Schedule Y is replaced by NDCT 2019 rules