Category: Study conduct

Title: Audio Visual (AV) recording of informed consent process for vulnerable participants and audio recording of informed consent process for clinical trials on Anti-HIV & Anti-Leprosy drugs.

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Author: Dr. Sukant Pandit
DM Resident

Signature with date Spandit 31/Dec/2022

Reviewer: Dr. Bhaskar Krishnamurthy
Assistant Professor

Signature with date 31-12-22

Dr. Bhaskar Krishnamurthy
Assistant Professor,
Department of Clinical Pharmacology,
Seth GSMC and KEMH,Mumbai -400 012.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date 31/12/22

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital
Parel, Mumbai - 400 012.

Table of Contents

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. 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.

Two years after the order from the DCGI office an amendment was made to the existing Drugs & Cosmetics (5th Amendment) Rules, 2015. This was noted as G.S.R. 611 (E) dated 31st July, 2015 as per which video recording of the informed consent process is mandatory only in case of Vulnerable Subjects in Clinical Trials of 'New Chemical Entity or New Molecular Entity' including procedure of providing information to the subject & its understanding on such consent, which shall be maintained by the investigator for record. It also mentions requirement of only 'Audio Recording' of consent process in case of Clinical Trials of Anti-HIV & Anti-Leprosy drugs.

2. Purpose

The purpose of this SOP is to describe the procedures for Audio-Visual (AV) & Audio recording, storage and archival of the informed consent and assent process for regulatory studies involving Vulnerable Subjects and Clinical Trials of Anti-HIV & Anti-Leprosy drugs.

3. Scope

This SOP applies to all those regulatory clinical trials involving Vulnerable Subjects and Clinical Trials of Anti-HIV & Anti-Leprosy drugs, 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 and Audio recording of the informed consent process involving Vulnerable Subjects and Clinical Trials of Anti-HIV & Anti-Leprosy drugs, storing and archiving without violating the participant confidentiality.

5. Applicable rules, regulations and guidelines

- G.S.R. 611 (E) of Drugs & Cosmetics (5th Amendment) Rules, 2015 dated 31st July, 2015.
- 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
- New Drugs and Clinical Trials Rules, 2019
- Ethical Guidelines for Biomedical and Human Research involving Human Participants, ICMR 2017
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.

6. Reference to other applicable SOPs

- SOP No D 05/05: Administering and documenting informed consent
- SOP No D 18/05: Archiving documents

7. Detailed Instructions

All basic principles and procedures for the administration and documentation of the informed consent process (Reference SOP No. 05/02: Administering and documenting informed consent) will be applicable besides those mentioned below:

1. AV recording of the entire informed consent process is mandatory only in case of Vulnerable Subjects in Clinical Trials of 'New Chemical Entity or New Molecular Entity' and audio recording of consent process in case of Clinical Trials of Anti-HIV & Anti-Leprosy drugs.
2. AV recording or audio recording must be done of any re-consenting procedure followed.
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 by AV Recording (all except 'point b' in case of only Audio Recording):

a. The informed consent process should be carried out in the designated area in Phase I unit (unless patient is on a bed in Ward 24, when the following conditions should be met, in any case) that is
   i. Free from disturbance
   ii. Well lit
   iii. Ensures privacy and confidentiality 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 backup (at least 2 hours)

- Show non-editable date, time and language of consent to be taken on video frame (preferably)

c. Mike system
d. All the required accessories (e.g. pen for signatures)
e. Computer with CD/DVD writer
f. Blank CDs/DVDs with cover
g. External Hard disk (at least 1 TB)

7. **Before starting the informed consent process (and the AV or Audio recording of the same)**
   a. Ensure that all the necessary equipment mentioned above are functional.
   b. The potential vulnerable 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.
   c. The potential vulnerable 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.
   d. The potential vulnerable participant/LAR/impartial witness should give written consent for AV recording process with sign, date and time which should be counter signed by the investigator/designee with date and time.
   e. All these signatures, version and language of the ICD should be captured at the beginning of AV recording process.
   f. Ensure that the checklist is prepared a priori to cover all important aspects of the AV consenting process.

8. **Actual AV or Audio recording process**

- The PI/Co-I/medically qualified person delegated by the PI and the potential vulnerable 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 (not necessary for Audio Recording of Consent Process).
- 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.
- Vulnerable 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 vulnerable participant cannot give consent. Vulnerable 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 vulnerable 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 Informed Consent Process should be carried out as per **SOP 05/05: Administering and documenting informed consent.**
- **The participant should be allowed to read the consent document**
- The PI/Co-I/medically qualified person delegated by the PI should explain <u>all</u> the elements of the approved ICF in the language best understood by the potential vulnerable participant
- Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential vulnerable 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 the ICD to 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.

- If the potential vulnerable participant/ LAR (wherever applicable) agrees to participate in the trial, he/she should be asked questions to assess his/her understanding of the important aspects of the clinical trial. **(Please refer to Appendix 1- Informed consent process assessment tool)**
- The participant/LAR (wherever applicable) should be invited to sign the informed consent form only after satisfactory answers (in the investigator's/designee 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 initials/thumb print at the end, if he/she agrees with the statement.
- The complete signing process should be recorded and the subject should also write the date and time along with signature.
- 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 with date and time in the consent form.
- The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form with the time 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 using a dedicated laptop in which the original recording will be stored.
10. No editing should be done on the recording so as to maintain authenticity.
11. 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.

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 Hard drive. The CD should be filed in the participant binder.

13. **Archival**

    a. The CDs will be archived with each participant binder (Refer **SOP No 18/02: Archiving documents)**

    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.**Appendices**

Appendix 1

Informed consent process assessment tool

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(s)?
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 injury during your participation, you will be treated for free and will be compensated for this injury if it is related to the drug?
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 all your questions about the research been answered?

Appendix II

Checklist for AV Consenting Process

Subject ID:

Initials:

Date of AV consent Process:

1. **Pre-recording checklist:**	
	Please tick
Crosschecked IEC approved/ PI signed version and Language of Consent form	YES /NO
Equipment is functioning correctly	YES /NO
All parties (trial team personnel conducting the consent, the participant 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

2. **AV recording:**	
Whether consent for AV recording already taken before start of recording	**Please tick**
It is taken in front of the camera	YES /NO
Reconfirm that the video recording frame includes all concerned parties and timestamp in video frame/Clock showing actual date time is present	YES /NO
Consent is being taken in a language the participant understand best and is literate in	YES /NO
The member of the research team should state the • Date • Time • Title of the research protocol • Language of the written informed consent document.	YES /NO

All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. Showing the consent form in the camera which is going to be used for the study.	YES /NO
At any point during the recording, any participant may request for a break (Eg. to go to the bathroom or answer a phone). 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
The actual signing process by all concerned parties should also be recorded.	YES /NO
Elements which should feature in the informed consent process • Purpose of the study • Treatment allotment • Randomisation procedure • Follow- up • Benefits/risks • Compensation for participation • Compensation for trial related injury • Nominee and details • Voluntariness for participation • Right to withdraw from the study • Contact details for further information	YES /NO
Informed that the recording may be shown to government agencies or members from the IEC	YES /NO
Questions asked by the participant are answered satisfactorily	YES /NO
Whether ample time was given to read and understand the consent as per the content	YES /NO
Opportunity to discuss the same with the family members	YES /NO
Reading out by the participant the statements mentioned in Informed Consent	YES /NO

Whether checked for participants understanding of the informed consent process	YES /NO
Documentation of signatures of all those involved in the Informed Consent Process.	YES /NO
Clarity and completeness of AV recording (pages vis-a- vis timing)	YES /NO
Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labeled CD	YES /NO

3. Post recording checklist:	
The narrative for AV consenting process will be the source document and is written and signed by the person taking the informed consent.	YES /NO
Rename the file with the unique number for the patient on this research protocol.	YES /NO
Make backup one by copying that file onto the dedicated external HDD that shall be used to document all consent AV recording for a specific research protocol.	YES /NO
This external HDD should be suitably labeled and password protected	YES /NO
Store the external HDD in a secure location to ensure confidentiality.	YES /NO
Make backup two by copying that file onto remote cloud storage with encryption using the computer with internet access.	YES /NO
This should also be suitably located, labeled and password protected.	YES /NO

Reviewer: Dr. Bhaskar Krishnamurthy
Assistant Professor

Signature with date 31-12-22

Dr. Bhaskar Krishnamurthy
Assistant Professor.
Department of Clinical Pharmacology.
Seth GSMC and KEMH,Mumbai - 400 012.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date 31-12-22

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hos.
Parel, Mumbai - 400 012.