Category: Study conduct
Title : Audio Visual (AV) recording of informed consent process
SOP No / Version No: DCP 27/08
Date first effective: 1 Jan 2026 **Review date: 31 Dec 2026**

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Category: Study conduct

Title: Recording, Storage, and Archival of Audio Visual Informed Consent

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1. Background

Audio-Visual (AV) recording of the informed consent process was mandated by the DCGI office order dated 19 November 2013, following the Hon'ble Supreme Court order (21 October 2013), to ensure that clinical trial participants are adequately informed about study details, risks, benefits, and their rights, thereby safeguarding voluntary participation.

Subsequently, G.S.R. 611(E) dated 31 July 2015 under the Drugs & Cosmetics Rules specified that AV recording is mandatory for **vulnerable participants** in clinical trials of New Chemical Entities (NCEs)/New Molecular Entities (NMEs), while **audio recording** is required for trials involving Anti-HIV and Anti-Leprosy drugs.

As per the New Drugs and Clinical Trials Rules, 2019, these requirements are retained and reinforced, emphasizing AV recording for vulnerable populations, ensuring proper documentation of the informed consent process, and maintaining recordings securely for regulatory compliance and inspection.

2. Purpose

To describe the procedures for AV/audio recording, storage, and archival of informed consent/assent in studies involving vulnerable participants and Anti-HIV/Anti-Leprosy trials.

3. Scope

This SOP applies to DCGI-approved clinical trials involving vulnerable participants and Anti-HIV/Anti-Leprosy studies requiring documentation of informed consent/assent process.

4. Responsibilities

The Principal Investigator (PI), Co-Investigator, or delegated medically qualified staff responsible for obtaining informed consent shall ensure AV/audio recording, secure storage, and archival of the consent process while maintaining participant confidentiality

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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 1st January 2026.
- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, accessed on 1st January 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, accessed on 1st January 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, accessed on 1st January 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, accessed on 1st January 2026.
- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_Bio Medical_Research_Involving_Children.pdf accessed on 1st January 2026.

6. Reference to other applicable SOPs

- SOP No 05/06: Administering and documenting informed consent
- SOP No 18/06: Archiving documents

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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:

- **AV/Audio Recording Key Procedure**
  - AV recording is mandatory for vulnerable participants in NCE/NME trials, and audio recording for Anti-HIV/Anti-Leprosy trials.
  - Re-consenting must also be recorded.
  - If the participant cannot consent, recording must include the Legally Acceptable Representative (LAR); an impartial witness is required for illiterate participants and should be part of the recording.
  - Assent (where applicable) must be AV recorded.
- **Pre-Recording Requirements**
  - Ensure designated area (unless patient is on a bed in Ward 24) with privacy, adequate lighting, and minimal disturbance.
  - Verify functional equipment: camera (resolution: at least 1280 *720), audio system, adequate storage (at least 4 GB), Sufficient battery backup (at least 2 hours), all the required accessories (eg. Pen for signatures), computer, blank CDs with cover, external hard disk (at least 1 TB)
  - Obtain written consent for AV recording prior to initiation.
  - Inform participant/LAR/witness about:
    - Purpose of recording
    - Confidentiality
    - Potential review by regulatory authorities/IEC
  - Capture Informed consent Document (ICD) version, language, and signatures at the start of recording.

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- **During Recording**
  - Record date, time, study title, and investigator introduction.
  - Capture participant/LAR (and witness, if applicable) identification and details.
  - Ensure the process is conducted in a language understood by the participant.
  - Record clearly:
    - Explanation of study (purpose, risks, benefits, rights)
    - Participant queries and responses
    - Confirmation of understanding
  - Allow pauses if needed; restart with date and time documentation.
  - Record complete consent/assent signing process with date and time.
  - Ensure continuous, clear audio/video coverage; no editing permitted.
- **Post-Recording & Storage**
  - Check recording for clarity, completeness, and audibility.
  - Store in a password-protected system with restricted access. (only PI and members of study team designated by PI)
  - Transfer to labeled media (CD/Hard drive/Pen drive) with study ID, participant ID, date, and recording details.
- **Archival**
  a. Archive recordings securely with participant records: individual participant recordings may be stored on CD (if required), while password-protected electronic backups (hard disk/pen drive) are maintained centrally for all study participants, as per sponsor requirements [mentioned in the Clinical Trial Agreement (CTA)] **(Refer SOP No. 18/06: Archiving Documents).**
  b. Ensure confidentiality and controlled access.
  c. Retain recordings as per regulatory requirements (minimum 5 years or as applicable); delete original device copy after proper archival. [As per Clinical Trial Agreement (CTA)]

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Appendix I

Checklist for AV Consenting Process

Participant 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

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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

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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

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Signature & date of PI or Designee:

Reviewer as appropriate:

Signature with date

01/Jan/2026

Approved by Head of Department: Dr. Nithya Gogtay

Professor and Head

Signature with date

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