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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Ti**tle:  **AudioVisual Recording (AV) of Informed Consent** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**18.1 Purpose:**

Regulations in India have made it mandatory for Audio Visual (AV) recording of the informed consent for regulatory clinical trials based on the order of the Hon’ble Supreme Court of India dated 21st October 2013. This will ensure that the process of informed consent is documented in a manner to show that the participant subjects have voluntarily agreed to participate in the clinical trial after they have understood the details of the study and their rights. The objective of this SOP is to ensure that the for Audio-Visual (AV) recording is performed in compliance with the regulatory requirements and that the recording is stored as well as archived in a fail safe manner.

**18.2 Scope:**

The scope of this SOP is for all regulatory clinical trials, requiring and receiving approved of the DCGI, and is limited to the documentation of the informed consent process. It is not meant to replace the written informed consent.

**18.3 Procedure**

This SOP is in addition to the written informed consent process. Hence this is in ADDITION to the written informed consent process that was being carried out at [institution].

AV recording is applicable to:

* Informed consent
* Re-consent
* Assent

AV recording should be carried out in an area that ensures:

* Confidentiality
* Adequate lighting and Minimal background noise to allow AV recording
* Equipment (Minimum recommendations)
* Camera with video recording capability in High Resolution (HD) – 1080 and higher
* Storage device/ memory card compatible with the camera and having sufficient memory (at least 1 GB) (source document)
* Audio capture capability
* External HDD (minimum capacity 100 GB) (backup1)
* Computer with internet access
* Remote cloud storage with encryption (backup 2)

Personnel required:

* Person to handle the video camera
* Medically qualified and authorized member of the research team who will conduct the informed consent procedure
* Patient who is willing to give the consent and participate in the research.

Additional personnel in circumstances as outlined below:

1. Scenario one: Where written consent document is in a language in which the medically qualified authorized member of the research team is proficient and the patient is able to sign (literate).

No additional personnel required.

1. Scenario two: Where written consent document is in a language in which the medically qualified authorized member of the research team is proficient and the patient is going to put thumb impression (illiterate)

Impartial witness required.

1. Scenario three: Where written consent document is in a language in which the medically qualified authorized member of the research team is not proficient and the patient is able to sign (literate).

Translator required (person familiar with the language of the written consent document as well as English/ language that the medically qualified authorized member of the research team is proficient in).

1. Scenario four: Where written consent document is in a language in which the medically qualified authorized member of the research team is not proficient and the patient is going to put thumb impression (illiterate)

Impartial witness and translator required.

1. Scenario five: In case the patient is unable to give consent for medical or legal reasons, the legally acceptable representative (LAR) should also be included in the above four scenarios as applicable.

Legally acceptable representative required.

**Pre-recording checklist:**

* Equipment is functioning correctly
* All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording.
* All parties are reminded that this AV recording is in compliance with regulatory requirements
* 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.

**AV recording:**

Reconfirm that the video recording frame includes all concerned parties.

The member of the research team should state the date, time, title of the research protocol and the language of the written informed consent document.

All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research.

If LAR is involved, he/she should state relation to participant.

If translator is involved, he/she should confirm that he/she is proficient in the language of the informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process.

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.

The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point.

The actual signing process by all concerned parties should also be recorded.

**Post recording checklist:**

The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording.

Rename the file with the unique number for the patient on this research protocol.

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.

This external HDD should be suitably labeled and password protected.

Store the external HDD in a secure location to ensure confidentiality.

Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access.

This should also be suitably located, labeled and password protected.

**Storage and Archival**

The storage device/ memory card which is the source document will be appropriately labeled, sealed and suitably attached to the written informed consent document. It will be stored and archived along with other confidential research protocol related documents.

**18.4 Staff responsible for Implementation:**

This SOP is applicable to all personnel authorized to conduct the informed consent process. Hence it is applicable to the Principal investigator, Co-Investigator(s) and all other medically qualified trial personnel authorized by the Principal Investigator for obtaining the informed consent.

**REFERENCES**

These SOPs are designed comply with the following rules and regulations:

* Order of 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
* Schedule Y (Jan 2005) of Drugs and Cosmetics Act and its modifications
* Ethical Guidelines for Biomedical Research on Human Participants, Indian Council for Medical Research, Govt of India 2006
* International Conference on Harmonization; Good Clinical Practice Guidelines: May 1996
* Indian Good Clinical Practices 2001