AX10-V6.1/SOP 03/V6.1

Informed Consent Template for Audio-Visual Recording

Audio-video recording of the consent process (applicable for DCGI regulated studies in case of vulnerable participants in clinical trials of New Chemical Entity or New Molecular entity).

Protocol Number

Protocol Title

Sponsor
Name of Principal Investigator (Study Doctor)
Site Name & Address

(Institute)
Contact Number of the Study Doctor
Alternate Numbers for Contact
Patient ID:

The Indian Regulatory Authority Drugs Controller General, India (DCGI) (an authority which approves and monitors conduct of clinical studies in India), who has approved/shall approve this study, has laid down the New Drug Clinical Trial,2019 Rules which states that 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 of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. This is in addition to the requirement of obtaining written informed consent.

Statement by the Participant/ LAR

By signing this form, I hereby give my consent to the study doctor and Institute for an audio-visual recording of my informed consent process, including the procedure of providing information to me and my understanding on such consent, preservation/ archival of such audio-visual recording and related documentation as per Regulatory requirements, under the responsibility of the Institute and study doctor. The extent of this recording is understood to be limited to discussion of contents of Informed Consent Form for this study.

The study doctor and Institute will adhere to the principles of confidentiality for such an audio-visual recording of my informed consent process, however

- □ I understand that such an audio-visual recording of my informed consent process may be seen by the representatives of the Central Licensing Authority office and/or Ethics Committee.
- □ I understand that my consent is voluntary and is applicable to the entire duration of my participation in this study.
- □ If I refuse to provide an audio-visual recording of my informed consent process, in compliance with regulations I would not be able to participate in this study.
- □ If I have any questions about my data protection or privacy rights under this form, I understand that I may contact the Study Doctor.
- □ I confirm that I have read and understood the contents of this Consent Form and have had the opportunity to ask questions before signing it.

To be completed by Participant/ LAR/ Impartial Witness, as applicable

Participant's name (print):	
Participant's Signature/Thumb impression & date:	
Legally Acceptable Representative name	
Legally Acceptable Representative Signature/Thumb impression & date(if applicable):	
Impartial Witness's name:	
Impartial Witness's signature & date(if applicable):	
Name of PI or Co-PI/Co-I:	
PI or Co-PI/Co-I sign & date:	

Note: Copy of the Participant Information Sheet and duly filled in Informed Consent Document should be handed over to the participant or his/her attendant

A copy of the participant feedback form also needs to be provided along with the copy of the signed informed consent form.