**AX10-V6/SOP 03/V6**

**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 this Study, has laid down new Rules that in addition to the requirement of obtaining written informed consent, an audio-visual recording of the informed consent process of each trial participant, including the procedure of providing information to the participant and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality and such audio-visual recording and related documentation would be preserved for a period of 15 years under the responsibility of the Institute and study doctor.

**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 for a period of 15 years under the responsibility ot 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 DCGI 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: |  |
| Legal Acceptable Representative name |  |
| Legal 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: |  |