Annexure 3

AX 03/SOP 12/V5

Guidance document for audiovisual recording of AV consent Process

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. 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. 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

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. 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. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. 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. YES /NO
6. 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
7. 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. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. 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. YES /NO
2. 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. YES /NO

3. Rename the file with the unique number for the patient on this research protocol. YES /NO

4. 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

5. This external HDD should be suitably labeled and password protected. YES /NO

6. Store the external HDD in a secure location to ensure confidentiality. YES /NO

7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO

8. This should also be suitably located, labeled and password protected. YES /NO