MONITORING OF AUDIOVISUAL RECORDING OF THE INFORMED CONSENT PROCESS [Clinical Trial]

(Please tick the box corresponding to the answer)

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| --- | --- | --- |
| **Sr. No.** | **Observation** | **Yes/**  **No** |
| **1** | Facility where informed consent process should be carried out - (well lit, spacious, comfortable, aptly ventilated, free from noise, privacy ensured) |  |
| **Remarks:** |  | |
| **2** | The consent is taken in language the participant and/ or LAR understands best and is literate in |  |
| **Remarks:** |  | |
| **3** | Introduction of each person (person conducting the informed consent discussion with the participant/ legally acceptable representative (LAR)/ impartial witness) involved during informed consent process and information about necessity for audiovisual recording |  |
| **Remarks:** |  | |
| **4** | Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of  documentation as required by the government rules |  |
| **Remarks:** |  | |
| **5** | Information to the participant/ LAR and impartial witness (as applicable)  that the confidentiality of information and privacy of participants will be assured |  |
| **Remarks:** |  | |
| **6** | Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to the Government agencies or the Members from the Institutional Ethics Committee |  |
| **Remarks:** |  | |
| **7** | Explanation or narration by the person conducting the informed consent  Discussion |  |
| **Remarks:** |  | |

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| --- | --- | --- |
| **8** | Questions asked by the potential participant/LAR are answered satisfactorily |  |
| **Remarks:** |  | |
| **9** | Ample time and opportunity is given to the Participant/ LAR to read and understand the information in the informed consent document or discuss the same with the family members |  |
| **Remarks:** |  | |
| **10** | Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent and stating whether participant agrees or not for each statement  (All the statements written in the Informed Consent document are read out by the Participant/ LAR (or have been read out by an impartial witness) and clearly stating whether the Participant/ LAR agrees or not for each statement) |  |
| **Remarks:** |  | |
| **11** | Documentation of Date and Signatures of all those involved in the process of filling the Informed Consent document |  |
| **Remarks:** |  | |
| **12** | Clarity and completeness of AV recording |  |
| **Remarks:** |  | |
| **13** | Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labeled CD with access allowed only to the principal investigator and designated members of the study team |  |
| **Remarks:** |  | |
| **Name and Signature of the Monitor [with Date and Place]** | | |

Signature of the Chairperson, IEC-CHARUSAT with the Date