Format for Audio Visual Consenting Process
INSTITUTIONAL ETHICS COMMITTEE
H M PATEL CENTRE FOR MEDICAL CARE AND EDUCATION, KARAMSAD

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

(Please tick the box corresponding to the answer)

Sr. No.	Observation	Yes/ No
1	Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured)	
Remarks:		
2	The consent is taken in language the participant/LAR understands best and is literate in	
Remarks:		
3	Introduction of each person (person conducting the informed consent discussion 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 is assured	
Remarks:		
6	Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC	
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	Allowing ample time and opportunity to read/understand the information in the informed consent document or discuss the same with 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	
Remarks:		
11	Documentation of signatures of all those involved in the Informed Consent Process	
Remarks:		
12	Clarity and completeness of AV recording	
Remarks:		
13	Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD with access allowed only to the principal investigator and designated members of the study team	
Remarks:		
Signature of monitor [with date]		

Signature with date
Chairperson, IEC