This template is adapted from other Institutes written for a pre-adolescent or young adolescent, which is developed by referring to the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt/modify their own ICFs (should be drafted in simple, non-technical language) based on their required study.

Notes: The informed consent form consists of two parts with common questionnaire: (a) the information sheet, and (b) the consent certificate. Please do not delete any sections. If any portion is not relevant to your study, please mark it as NA.

a The basic procedure of the informed consent process and documentation of the informed consent will be the same.

b The potential participant/legally acceptable (or authorized) representative (LAR) and impartial witness (if applicable) should be informed that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules and the confidentiality of the same is assured.

c The potential participant/LAR and impartial witness (if applicable) should be made aware that his/her recording may be shown to government agencies or members from the IHEC.

d If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the LAR. In such case, the LAR is requested to follow the AVR consent procedure.

e If the participant/ LAR is illiterate, then an impartial witness is needed. This person should also be in the frame of camera while recording is done.

f AVR (audio visual recording) should be done of assent wherever applicable.

g The following infrastructure should be available prior to counselling of potential participant:

1. The informed consent process should be carried out in a room designated for this purpose (unless patient is bedridden), which is well lit, free from disturbance and ensures privacy to the participant.
2. Camera having video facility with good resolution (at least 640 x 480), sufficient memory (at least 4-8 GB), and show tamper proof date and time on video.
3. Computer with USB ports and external hard disk (at least 1 TB)

AVR process

1. The audio recording is performed for all the participants independently.
2. Ensure that all the necessary equipment mentioned above are functional.
3. The designated person conducting the informed consent discussion and the potential participant/LAR (and an impartial witness, if applicable) should sit comfortably facing each other in such a way that their faces will be captured in the frame simultaneously.
4. The person conducting the informed consent discussion should introduce himself/herself by name, designation and his/ her role in the research, current date, and time.
5. Participant/LAR (and an impartial witness, if applicable) should be requested to introduce his/her name, age, and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why he/she cannot give consent (if applicable).
6. Participant/LAR should also state the language he/she understands best and is literate in.
7. All above points are captured in the recording. The Informed Consent Process should be carried out.
8. Explanation or narration by the person conducting the informed consent discussion, all the questions asked by the potential participant/LAR and answers given to them should be loud and clear and recorded.
9. The following minimum elements should feature in the recording of the informed consent process: introduction of each person (person conducting the informed consent discussion participant/LAR/ impartial witness) involved during informed consent process and information about necessity for audio visual recording, entire informed consent discussion, reading out the statements mentioned in Informed Consent Form as per schedule-Y by participant/LAR and stating whether he/she agrees or not for each statement, documentation of signatures of all those involved in the Informed Consent Process.
10. At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the of stopping. When he/she returns the recording from the point where it was stopped before shall be resumed as mentioned before stating clearly again the date and time of recording.
11. The recording will be stopped after thanking the participant.
12. The recording should be checked for completeness and clarity of both audio and video recording using a dedicated laptop in which the original recording will be stored.
13. No editing should be done on the recording so as to maintain authenticity.

14. The laptop should be password protected. The password will be known only to the principal investigator and designated members of the study team.
15. The recording should be then transferred to a USB labelled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting) and archived in a dedicated Hard drive.
16. The soft copies of the recordings will also be stored in a password protected hard drive.
17. The original recording in the laptop/computer will be deleted.