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.

[Informed Assent Form for _____]

Study Title:

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on several different groups of individuals. For example, children with malnutrition, and children without malnutrition.

(This informed assent form is for children between the ages of 7 – 18, who attend clinic X and who we are inviting to participate in research Y.)

Name of Principle Investigator:
Affiliation:
Name of Sponsor:
Name of Project and Version:

This Informed Assent Form has two parts:
(a) Information Sheet (gives you information about the study)
(b) Certificate of Assent (this is where you sign if you agree to participate)

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction
Introduce yourself and explain the parents that you are inviting them to allow their child to participate in your research activity.

Purpose
Explain the purpose of the research in clear simple terms. Why the research is being done and what is expected from the results. Also explain why you need to conduct research with children.

Type of research Intervention
Briefly state the intervention and elaborate upon in the procedure sections.

Selection of Participants
It is natural that parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned. State clearly why you have chosen their child to participate in this study.

Voluntary Participation
It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning. Indicate clearly that they can choose for their child to participate or not and reassure they will still receive all the services they usually do if they choose not to participate. Also inform them that their child will also have input into the decision. This can be repeated and expanded upon later in the form as well.

Procedure
Indicate when and how (step wise) the research will take place and where.

Duration
Clearly indicate about the time commitments may be required from the child, including the parent(s) for the study. Include both the duration of the study and follow-up, if relevant.

Risk and Discomfort
Explain any risks or discomforts including any limits to confidentiality

Benefits
Describe any benefits to their child, to the community, or any benefits which are expected in the future because of the research.

Reimbursements
WHO does not encourage incentives beyond reimbursements for expenses incurred because of participation in research. The expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined within the host country context. State clearly what you will provide the participants because of their participation.

Confidentiality
Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality.

Sharing of Research Findings
Include a statement indicating that the research findings will be shared in a timely fashion, but that confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform the parent that the research findings will be shared more broadly, for examples, through publications and conferences.

Right to refuse or withdraw
Explain again the voluntary nature of consent. Also explain that their child will be asked to agree - or assent - and that the child's concerns and wishes will be taken very seriously.

Whom to Contact
Provide the name and contact information of someone who is involved, informed and accessible (who is part of the investigating team – PI or Co-PI). State also that the proposal has been approved and how.

This proposal has been reviewed and approved by (name of the IHEC), which is a committee, whose task is to make sure that research participants are protected from harm. If you wish to find about more about the IHEC, contact (name, address, telephone number).

PART 2: Certificate of Consent
This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the requirements of the study as outlined in the Information Sheet.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant ___

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Print Name of Principal Investigator_____

Signature of Principal Investigator_____

Date _____
Day/month/year