INFORMED PARENTAL CONSENT TEMPLATE FOR RESEARCH INVOLVING CHILDREN (QUALITATIVE STUDIES)

(*For use with participant observation, focus group discussions, interviews, and surveys. Language used throughout the form should be at a level appropriate to the child's age and development.*)

[INSTITUTIONAL LETTER HEAD]

Informed Consent Form for [Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.]

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

PART I: INFORMATION SHEET

INTRODUCTION

Briefly state who you are and explain that you are inviting them to have their child participate in research which you are doing. Inform them that may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want their child to participate or not. Assure the parent that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

PURPOSE OF THE RESEARCH

Explain in lay terms why the research is being done and what is expected from the results. Explain why you need to conduct the research with children.

TYPE OF RESEARCH INTERVENTION

Briefly state the intervention. This will be expanded upon in the procedures section.

SELECTION OF PARTICIPANTS

State clearly why you have chosen their child to participate in this study. Parents may wonder why their children have been chosen for a study and may be fearful, confused or concerned.

VOLUNTARY PARTICIPATION

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. 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.

PROCEDURES

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

Explain the type of questions that the participants are likely to be asked in the focus group discussion, interview or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate parents' concerns and protective responses, and address these. Parents may be concerned that if researchers talk to their children about sexuality it may encourage them to explore sexual activities with their peers. Other concerns may include disbelief that their child is ready to talk about sexuality, or parents may be personally embarrassed.

DURATION

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

RISKS AND DISCOMFORTS

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 as a result of the research.

REIMBURSEMENTS

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

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. Note that with focus groups confidentiality cannot be guaranteed because what is said within the group becomes common knowledge. Participants can be asked not to share outside of the group but this does not guarantee confidentiality.

SHARING THE 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.

WHO TO CONTACT

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

PART II: 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.

This section is mandatory

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 have 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 or Guardian: _____
Date: [MM/DD/YYYY]

If Alternatively Schooled

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: [MM/DD/YYYY]

STATEMENT BY THE RESEARCHER OR 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 that the following will be done:
1.

2.
3.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her 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 or person taking the assent _____
Signature of Researcher or person taking the assent _____
Date: <MM/DD/YYYY>

An Informed Assent Form will _____ OR will not _____ be completed.