**MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES**

**SCHOOL OF MEDICINE RESEARCH AND ETHICS COMMITTEE (SOMREC)**

**ASSENT FORM TEMPLATE**

**Title of Research Study:**

**Investigators:**

State the names, contacts and institution of affiliation for the study investigators.

**Background Information:**

Give a brief background and rationale for the proposed research.

**Why is this research being done?**

Brief description of the purpose of the study and why the participant is being asked to participate. A statement that the study involves experimentation and what part of the study is experimental.

**Why am I being asked to take part in this research study?**

Insert description of why they are being asked to take part.

**How long will the research last?**

Insert the estimated duration the research participant will take in the research project.

**What happens if I take part in this research?**

Description of the procedures of the study explaining how a participant will be involved and what is required of the participant.

**Do I need to answer all the questions or accept all study procedures if I take part in this research?**

Participants should be informed that they have a right to refuse to answer any questions that give them discomfort.

**How will I benefit from taking part in this research?**

Explain the anticipated direct /indirect benefits of conducting the research to the participant, community and the entire scientific world.

* A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant.

**Are there any risks/disadvantages of taking part in this research?**

Explain the possible risks and discomforts a participant might experience while participating in the research].

**What happens to the information collected for the research?**

Include an explanation of how privacy will be maintained during the course of research and how confidential and sensitive personal information of the participant will be handled.

* Mention who you expect to have access to confidential information including a clause that: the local Research Ethics Committee (REC) and Uganda National Council for Science and Technology (UNCST) are entities which may have access to private information that identifies the research participants by name.

**What happens if I refuse to participate in this research?**

Participants should be informed that participation in the study is not mandatory and what possible alternatives are available other than participating in the study.

**Compensation related to research injuries:**

Explain what happens if a participant/child gets injured during the course of their participation. Who will cater for costs of treatment?

* In case of permanent damage, explain how the participant will be compensated.

**Time compensation for participation in the study:**

Explain if the participant will be compensated for participating in the study and how they will be compensated.

**Reimbursement:**

Explain how study related costs such as transport and medical bills will be catered for, if any is to be incurred by the participant.

**What if I have any questions about the research?**

State who the contact person is in case a participant has study related questions which the person obtaining assent cannot answer. Include their names and mobile phone number(s).

**Questions about participants rights:**

Explain how participants who have questions about their rights as research participants can have their queries addressed. Include the name of the REC Chairperson and mobile contact/number.

**Who has allowed the research to take place?**

Insert a statement that the study has been approved by an accredited Ugandan based REC. The name of the REC that granted approval should be stated.

**Assent:**

Statement of assent after understanding the study and a signature portion.

**STATEMENT OF ASSENT**

........................................................................... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at any time. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of the child/participant: …………………………………….………. Age……......

Signature/thumb print …………………………………Date …………………………….

Name of witness: ……………………………………………….………………………….

Signature……………………………………. Date………………………………………...

Name of person obtaining assent: ……………………………….……………………...….

Signature…………………………….……………Date ……………………………………

**Please note:**

All information should be written in its simplicity form and complex medical terms should be followed by explanations for comprehension by an eight-year-old child.