UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTEE

INFORMED CONSENT TEMPLATE FOR INTENDING RESEARCHERS

1. Title of the proposed study:

If it's too long and quite complicated add a brief title that participants easily comprehend.

2. Investigators:

Give the names (Principle investigator and Co-investigators), institutions and contacts of the investigators.

3. Introduce the research to the subject:

- A statement that informs a participant that a study is being done and her consent is being sought for possible participation,
- Briefly explanation of what is entailed in the consent, and instructions participant should follow when reading it.
- Options should be given for participant to read or the ICF to be read to the subject.
- Clarify the difference between research and care or service that person came to seek
- Emphasize voluntarism of participation that even when participant declines participation they will not be penalized. Will access care or whichever services they desire without hindrance. Subjects should also be alerted that they have a right to withdraw consent participation.

4. Background and rationale for the study:

Give a brief background and rationale for the proposed research.

5. Purpose:

- 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.

6. Procedures:

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

7. Who will participate in the study?

Brief description of the intended participants;' the expected total number and how long each will be required to be active in the study.

8. Risks/Discomforts:

Description of the possible risks and discomforts a participant might experience while in the study.

9. Benefits:

Anticipated benefits of conducting the study including possible benefits to the participant, community and the entire scientific world

10. Alternatives:

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

11. Cost:

The possible costs to be met during the conduct of the study as far as the particular participant is concerned. Explain the possible costs and who will meet the bill of paying for the costs.

12. Reimbursement:

State how participant costs in terms of travel and opportunity cost while they come to the study site will be met.

13. Compensation for participation in the study:

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

Also explain what happens if a participant is injured during their course of participation and how they will be treated. State how participants who suffer permanent damage will be compensated.

14. Contacts for concerns/Questions:

State how participants who have study related questions can reach investigators to answer such questions. Explain how participants who have questions about their rights as research participants can have their queries addressed by REC or CAB.

15. Statement of voluntariness:

State that participation in the proposed study is voluntary and participants may join on their own free will. Participants also have a right to withdraw from the study at any time without penalty.

16. Confidentiality:

The results of this study will be kept strictly confidential, and used only for research purposes. My identity will be concealed in as far as the law allows. My name will not appear anywhere on the coded forms with the information. Paper and computer records will be kept under lock and key and with password protection respectively.

17. Explain what signing or putting a thumb print on the consent form means

Participant must understand that by signing this form ,he /she does not waive any of his/her legal rights but merely indicate that has been informed about the research study in which he /she is voluntarily has agreed to participate. Signing often simply means the subject has understood information in the consent form and accepts to participate in the study.

Note: In case of sample storage form it may mean that participant has accepted or declined storage. Check box for either option should be included for participant to complete and clarify the decision.

18. Statement of Consent/Assent

The acknowledging statement that the information in the consent form has been read and explained to the subject, he /she understands ,the purpose of the study, what is going to be done (procedures), the risks, the benefits involved and his /her rights regarding study participation/consent withdraw, access to care, and confidentiality and has voluntarily accepted to participate the study.

A statement that a copy of this form will be provided to the subject

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Name of participant (Print)	Signature	Date

For consents obtained for child participation:

Name of child (Print)

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Name of caretaker (Print) Signature Date

Caretakers' relationship with the child ----------

Witness:

Statement that I attest that the information in this document was read to the participant /caretaker and she /he understands the purpose of the study, what is going to be done (procedures), the risks, the benefits involved and his /her rights regarding study participation/consent withdraw, access to care, and confidentiality and he /she voluntarily accepted to participate the study (allow her child to participate in the study.

To those that used thumb print for consent (Only):

a) **Individual participants:**

I attest that the participants' name is----------
- has placed a his/her thumbprint on this consent form on this date----------
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b) **Caretakers:**

I attest that the caretakers name is ----------
and has placed his/her thumbprint on this consent form to allow the child called ----------
---------- to participate in the study on this date----------.

Caretakers' relationship with the child ----------

Note: For children investigator could include line for another person that could sign for child participation e.g In incidences where father and mother are present at a session or another relative may consent also and support the mother to bring the child during study follow up. In this case the relationship to the child should be indicated.

_____ _____ _____

Name of witness (Print) Signature Date

(To consent process)

Note: Be specific if witness is not necessary during consenting of all participants eg witness to consent process for those using thumbprint only.

_____ _____ _____

Name of study staff Signature Date

Obtaining consent (Print)

Note: Include version and date for easy tracking of consent revisions (especially for studies with long follow –up periods).