MAKERERE UNIVERSITY COLLEGE OF HEALTH SCIENCES

SCHOOL OF BIOMEDICAL SCIENCES RESEARCH AND ETHICS COMMITTEE (SBSHD-REC)

INFORMED CONSENT TEMPLATE FOR INTENDING RESEARCHERS

Title of the proposed study:

Investigators :
Give the names, contacts and institutions of the investigators.

Background and rationale for the study:
Give a brief background and rationale for the proposed research.

A description of sponsors of the research project and the organizational affiliation of the researchers:

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.

The estimated duration the research participant will take to in the research project:

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

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.

Risks/Discomforts:
Description of the possible risks and discomforts a participant might experience while in the study.

Benefits:
Anticipated benefits of conducting the study including possible benefits 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

Confidentiality:

Explanation of how privacy will be maintained during the study and how confidential and sensitive personal information to the participant will be handled. Please mention who you expect to have access to confidential information.

- Should also include a clause that: the local Research Ethics Committee (REC) and Uganda National Council for Science and Technology (UNCST) as entities which may have access to private information that identifies the research participants by name.

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.

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.

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.

Reimbursement:
State how participant costs in terms of travel and opportunity cost while they come to the study site will be met. (Transport, time and meals)

Questions about participants rights:
Explain how participants who have questions about their rights as research participants can have their queries addressed.

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.

Dissemination of results:
A statement that research participants will get feedback on findings and progress of the study and that any new information that affects the study or data that has clinical relevance to research participants (including incidental findings) will be made available to research participants and/or their health care providers.

Ethical approval:
A statement that the study has been approved by an accredited Ugandan based REC
Consent:

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

STATEMENT OF CONSENT/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 anytime. 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 ……Signature/thumb print of participant ……Date ……

Name ……Signature of parent/guardian for minors (If applicable)…Date ……...

Name……Signature of witness (if applicable)……Date…….

Name …….Signature of interviewer/Person obtaining informed consent ……Date …….