MAKERERE UNIVERSITY SCHOOL OF HEALTH SCIENCES RESEARCH AND ETHICS COMMITTEE (MAKSHS-REC)

RECRUITMENT INFORMED CONSENT FORM TEMPLATE FOR RESEARCH PARTICIPANTS AGED 18 YEARS AND ABOVE (ALSO NOTE THAT E-CONSENT SHOULD HAVE ALL THE ELEMENTS BELOW)
(Give your study informed consent form a title)

(Please ensure that all elements of informed consent provided below are included in your study informed consent form before submitting to MAKSHSREC for review and approval)

Title of the proposed study:
State the title of the proposed research study

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

Study sponsor
Give a brief description of the sponsors of the research project and the organizational affiliation of the researchers

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

Purpose:
Brief description of the purpose of the study and why the participant is being asked to participate.

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, the approximate number of individuals participating in the research study and where the study is going to be conducted from?
Brief description of the intended participants, the expected total number, how long each will be required to be active in the study and a brief description of where the study will be conducted from.

Risks/Discomforts:
Description of reasonably fore seeable risks or discomforts that the research participant may experience while in the study. Note that it is ethically not appropriate to state that the study has got no risks because all studies have risks depending on the risk level.

Benefits of the research study:

A description of the benefits to the research participant and/or their communities that may reasonably be expected to result from the study including potential benefits of commercial value

Compensation for participation in the study:
State how participant's time spent and inconveniences experienced while participating in the research study will be compensated. Compensation is monetary and it depends on the time spent and level of insolvencies experienced. (Note: UGX:10,000 is the minimum time compensation amount).. Note that refreshments and meals are not compensation for research participation but a welfare aspect for study participation. Research participants may also receive free medical services. The compensation or medical services shall not be out of proportion as to induce individuals to participate in research. (Refer to the Uganda National Guidelines for Research involving Humans as Research Participants, Sept,2025).

In case the participant is injured during their course of participation in the study, state the medical treatment available and where further information may be obtained. State how participants who suffer permanent damage will be compensated. (A research related injury may be physical, social, economic or psychological).

For clinical trials, medical treatment and compensation shall be covered through the mandatory clinical trial insurance.

Reimbursement:
State how participant's transport reimburment and any other costs incurred related the study participation will be met. (Research participants who will be told to come to the study site will have to be reimbursed their transport. Transport reimbursement will depend on where the participants are coming from. (Note that UGX:10,000 is the minimum time compensation amount).

Additional costs to the research participant that may result from his or her participation in the research study.
An explanation of any additional costs to the research participant that may result from his or her participation in the research study.

Questions about the study:
State how participants who have study related questions can reach the investigators to answer such questions. (Put the names, local telephone number and email address of the principle investigator)

Questions about participants rights:
State that participants who have questions regarding their welfare and rights as research participants can have their questions addressed by the MakSHSREC . Vice Chairperson Dr.Kalidi Rajab on telephone number +256 776798978 or +256 0200903786)

Consenting in the language understandable to the research participant

State that the individual(s) obtaining informed consent shall be able to communicate in a language understandable to the research participant.

Research involving the collection of human biological materials/samples for research
If applicable to your research study, with regards to research involving the collection of human biological materials/samples, an explanation should be provided on how samples will be managed at the end of the study.

If the biological materials/samples will be stored for future use/research, separate consent should be obtained from the participant, (Get the informed consent template for the storage and future use of human biological materials/samples from MAKSHSREC office)

If human samples will be transferred/shipped outside Uganda for analysis, Material Transfer Agreement (MTA) will have to be submitted for review and approval. (Refer to the Uganda National Guidelines for Research involving Humans as Research Participants, Sept,2025).

Dissemination of study feedback or study findings and progress of the study
State how research participants and other relevant people or institutions will get feedback on the findings and progress of the study, for instance MAKSHSREC/IRB expects to receive study feedback from the research team.

Audio recording
Include a statement seeking for permission from research participants if the study will involve audio recordings.

Photograph
Include a statement seeking for permission from research participants if the study will involve taking photographs, video recordings or other visual images.

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.

Ccircumstances under which the researcher may terminate the research participant's participation
Provide an explanation of circumstances under which the researcher may terminate the research participant's participation

Ethical approval of the research study
State that the study has been approved by Makerere University School of Health Sciences Research and Ethics Committee /IRB) which is an accredited Ugandan based Research and Ethics Committee/IRB.

Confidentiality*:*

State that the information that will be collected will be kept anonymous and confidential in

accordance with the international and local ethical standards governing research involving humans as research participants. My identity will be concealed and my name will not appear anywhere on the coded forms with the information. The study team will be the only one with the authority to access the collected data. However, the School of Health Sciences Research and Ethics Committee and the Uganda National Council for Science and Technology (UNSCT) may have access to private information that identifies the research participants by name where applicable. The filled questionnaire or any other filled data collection form will be kept under strict lock and key, and information on computers will be kept confidential with password protection respectively. For any further questions, I may contact the Chairperson of the School of Health Sciences Research and Ethics Committee (MakSHSREC) on (+256) +256 776798978 / (+256) 0200903786 or Uganda National Council of Sciences and Technology on Tel: (+256)-041-4705500).

STATEMENT OF CONSENT (Keep this the way it is)

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I have been informed about the study in which I am voluntarily agreeing to take part. 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 research participant……Age……..

Signature/thumbprint

Date (DD/MM/YY)……

A witness for illiterate and mentally incapacitated or physically handicapped participants who signs with thumbprint

Name of Witness …….

Signature …….

Date (DD/MM/YY)…….....

Name of the person consenting……

Signature…………………………………………………………..

Date (DD/MM/YY) …………………………………………………..