

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

**INFORMED CONSENT TEMPLATE FOR STORAGE AND FUTURE USE SAMPLES  
(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)*

A separate informed consent form shall be used for samples, which are collected with the intention of being stored and used in future studies. The consent form, which is separate from the one used for enrollment of research participants into the study, shall include the following components:

**Title of the proposed study:**

**Investigators:**

Give the names, contacts and institutions 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 of sample storage:**

Explain to the participant the reason for storage of their samples

**Quantities of samples to be stored:**

State the amount of body fluids/materials to be set aside for storage.

**Place where samples will be stored:**

Name the place where the samples will be stored. In case shipping will be involved, the participant also has a right to know the country and institution where the samples will be shipped and stored.

**Period of storage**

How long will the samples be stored or kept?

**Cost for storage**

State how much it will cost you to store the samples

**Disposal plan for the stored samples**

Describe to the participant how the stored samples will be disposed off

**Measures to protect confidentiality:**

Participants should be assured of the safety and privacy of the samples donated for storage and future use. As well as the mechanisms put in place by the study team to ensure that there is no breach of confidentiality.

**Policies that will govern use of the samples in future research:**

Inform the participants; who will have access to their stored samples and that for any researcher to use the samples, ethical approval should be obtained.

Indicate whether participants will be re-consented whenever samples will be used to answer new research questions

**Potential risks and benefits of storing samples for future research:**

Specify the risks and benefits involved

**How samples will be shared in the future (it can be locally or internationally or both)**

In case samples are going to be shared with other researchers not part of this study to answer new research questions, indicate how the sharing will be done

**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 principal 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 MakSHSIRB Ag. chairperson Dr. Kalidi Rajab on telephone number +256 776798978 or +256 0200903786)

**Dissemination of study feedback or study findings and progress on the stored samples for future use**

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.

**Statement of voluntariness:**

State that the participant has a right to withdraw his/her stored sample at any time without penalty.

**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.

**Consent:**

Statement of consent after understanding the purpose for sample storage and future use and a signature portion.

**STATEMENT OF CONSENT**

..... has described to me purpose of storage, the risks, the benefits involved and my rights regarding this request. I understand that my decision to either donate my sample for storage or not in this study will not affect me or alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw my sample 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 and have my sample stored. 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 .....