

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

**INFORMED CONSENT FORM TEMPLATE FOR GENETIC RESEARCH STUDY**

**Introduction**

You are invited to participate in a research study that involves genetic testing. The purpose of this study is to [briefly describe the main objective of the study]. This consent form will explain the details of the study, the possible benefits and risks, and your rights as a participant. Please read it carefully and ask any questions you may have before you decide whether to join the study or not.

**What is genetic testing?**

Genetic testing is a process of analyzing your (DNA), which is the material that carries your genes. Genes are inherited from your parents and affect many aspects of your physical and mental health. Genetic testing can reveal information about your risk of developing certain diseases, your response to certain medications, your ancestry, and other traits.

**What will happen if I join the study?**

If you agree to join the study, you will be asked to [describe the procedures involved in the study, such as providing a blood or saliva sample, filling out a questionnaire, undergoing a physical examination, etc.]. The study will last for [specify the duration of the study] and you will be expected to [specify the number and frequency of visits or contacts].

Your sample will be sent to a laboratory where it will be analyzed for [specify the type and scope of genetic testing]. The results of the genetic testing will be used for [specify the purpose of the genetic testing, such as identifying genetic variants associated with a disease, comparing your genes with those of other participants, etc.].

**What are the possible benefits of joining the study?**

By joining the study, you may [describe the potential benefits for the participant, such as learning more about your health, contributing to scientific knowledge, receiving compensation, etc.]. You may also benefit from [describe the potential benefits for the society, such as advancing the understanding of a disease, developing new treatments, improving health care, etc.].

### **What are the possible risks of joining the study?**

There are some risks associated with genetic testing and participating in a research study. These include:

- Physical risks: [describe the possible physical harms or discomforts that may result from the procedures involved in the study, such as pain, bleeding, infection, allergic reaction, etc.].
- Psychological risks: [describe the possible emotional or mental distress that may result from the genetic testing or the study, such as anxiety, depression, guilt, anger, confusion, etc.].
- Social risks: [describe the possible negative consequences that may result from the disclosure or misuse of the genetic information, such as discrimination, stigmatization, loss of privacy, conflict with family or friends, etc.].
- Legal risks: [describe the possible legal implications that may result from the genetic testing or the study, such as affecting your eligibility for insurance, employment, education, etc.].

### **How will my privacy and confidentiality be protected?**

Your privacy and confidentiality are very important to us. We will take the following steps to protect your personal information:

- We will assign you a unique code number that will be used to label your sample and your data. Your name and other identifying information will not be linked to your code number.
- We will store your sample and your data in a secure location that can only be accessed by authorized personnel. We will not share your sample or your data with anyone outside the research team without your permission.
- We will use encryption and other methods to protect your data when it is transferred or stored electronically. We will not include your name or other identifying information in any reports or publications based on the study.
- We will follow the laws and regulations that protect your privacy and confidentiality.

### **Will I receive the results of the genetic testing?**

[Specify whether the participant will receive the results of the genetic testing or not, and if so, how and when they will receive them. Also, specify whether the results will be clinically

validated or not, and whether the participant will have access to genetic counselling or other support services.]

**What are my rights as a participant?**

Your participation in this study is completely voluntary. You have the right to:

- Ask questions and receive answers about the study at any time.
- Withdraw from the study at any time without any penalty or loss of benefits.
- Refuse to answer any questions or perform any procedures that you do not wish to.
- Receive a copy of this consent form for your records.

**Whom can I contact for more information?**

- **Questions about the study:** If you have any questions or concerns about the study, you can contact the study principal investigator or the study coordinator (Put the names, local telephone number and email address of the principle investigator)
- **Questions about participants rights:** Research 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

**Consent Statement**

I have read and understood this consent form. I have had the opportunity to ask questions and have them answered. I agree to participate in this research study and to provide a sample for genetic testing. I understand that I can withdraw from the study at any time. I have received a copy of this consent form for my records.

Name of research participant.....Age.....

Signature/thumbprint



Date (DD/MM/YY) .....

*(Witness for illiterate research participants who signs with thumbprint should be provided below)*

Name of Witness .....

Signature .....

Date (DD/MM/YY).....

Name of the person consenting.....

Signature.....

Date (DD/MM/YY).....