**PARTICIPANT ID:** …………………………

**INFORMED CONSENT FOR GENETIC TESTING**

**Study Title:**

**Introduction:**

*You/ your child is being invited to take part in a research study. Before you decide on behalf of yourself/your child, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not to allow yourself/ your child to participate in this research.*

**Purpose**

Every human body is made up of cells that contain genes, which are composed of DNA (deoxyribonucleic acid). These genes carry instructions that influence how the body functions and why individuals may respond differently to certain diseases or medications.

This study aims to examine genetic differences that may affect how people respond to treatment for *[insert disease e.g. Tuberculosis]*. Some people may have genes that make certain drugs work better or worse. By studying this, we hope to better understand the *[insert disease]* treatment outcomes and improve care in the future.

**Procedure**

If you agree to allow yourself/ your child to participate, a *[insert type of sample e.g., blood]* sample will be collected from you/him/her. This sample is in addition to any blood samples that will be drawn for the purpose of your/ your child’s medical care.

Your DNA will be analyzed and the DNA information obtained from your/your child’s sample will be used along with the other information collected from the main clinical trial in which you’re/ your child is a participant, to study the differences in response to drugs that is generally seen in people with *[insert disease]* that are receiving treatment of *[insert appropriate].*

The study may include future analysis of your genetic material for related research, with ethics committee approval. Your/ your child’s sample may be stored for a long time but not longer than *[5 years]*. If we do not use the samples, the samples will be destroyed after *[Insert duration]*. Your/ your child’s health and medical information collected for the study will be retained.

**Voluntary Participation**

Your / your child’s participation in this genetic research is voluntary. If you decide that he/she should not participate in the genetic research, your child may still participate in the main clinical trial. In connection with the genetic research, you will also be asked to sign this separate consent form (on behalf of your child) authorizing the use and disclosure of your/ your child’s unidentifiable health information for this additional study.

**Possible Risks or Discomforts**

You or your child may experience some physical discomfort during sample collection, such as a brief sting from a blood draw. In addition, there are potential non-physical risks associated with taking part in this study, such as emotional discomfort, risks associated with a breach of privacy or confidentiality. We believe that the risk of such improper disclosure of your/ your child’s information is minimal because we have adopted strict privacy and confidentiality procedures for this research. We will make all reasonable efforts to minimize any breach of confidentiality.

**Benefits**

There will be no direct benefit to you/ your child as a result of your/his/her participation in the genetic research as these tests are currently not planned during the study. It is possible that your/ your child’s participation may contribute to the knowledge of *[insert name of Disease]*, or may help in developing new drugs or methods to detect or treat *[insert name of Disease]*.

**Confidentiality**

The clinical study team at *[insert study site]* will be the only people who will know your personal information (name, phone number, and address). The study team will replace your/ your child’s personal information with a coded identification number when your/his/her samples are used.

You understand that it is possible, however, that members of regulatory authorities, such as the Uganda National Council for Science and Technology and other persons required by law may have access to the research results. Although results from this research may be published; any publication will not identify you/ your child.

**Withdrawal of Consent and Destruction of Samples**

You may withdraw your/ your parental consent and discontinue your/his/her participation in this genetic research described above without affecting your/his/her participation in the main study.

To withdraw your/ your parental consent, you must contact your study doctor or the research office at *[insert study site and phone number]*, because only he/she has access to all of your identifying information. If you withdraw your/ your parental consent for the genetic research during this time, you may request that your/ your child’s blood sample and DNA obtained from his/her blood sample be destroyed and no longer be used in research. Any research results obtained prior to your withdrawal of consent will however be used.

**Questions/ Information**

This study has been reviewed by the School of Biomedical Sciences Research Ethics Committee (SBSREC), Makerere University.You may contact the chairperson of SBSREC if you have any questions regarding your/ your child’s right as a study participant at any time, Dr. Moses Ocan at email: [biomedicalresearch62@gmail.com](mailto:biomedicalresearch62@gmail.com) or 0782 355 302.

If you or your child have any questions regarding this sample collection or genetic research or if you/ your child experiences an injury caused by the sample collection procedure, you should contact *[insert Principal investigator’s name, phone number, email and institution of affiliation]*.

**Genetic information sharing**

Your genetic data may be shared with other researchers for ethically approved studies related to the scope described in the initial consent form. No personally identifying information will be shared.

**Genetic Results Sharing**

In general, summary findings from the study (not linked to your identity) may be shared with the scientific community through publications, presentations, reports. Your/my child’s identity will remain confidential and will not be revealed in any reports or publications.

The results of the genetic testing performed in this study are primarily intended for research purposes. Your/ your child’s individual results may not be shared with you or your child unless they are scientifically valid, clinically significant, and actionable. If such findings are identified, and where appropriate resources are available, we may contact you to offer the option of receiving these results, along with genetic counseling to help you understand them.

Would you like to be informed if any such findings are discovered? Yes No

**Statement of consent:**

……………………………………………………. has explained to me what is going to be done, the risks, the benefits involved and my rights as a participant/ parent/ guardian in regard to genetic testing. I understand that my/ my child’s participation in this study is voluntary and that I may refuse/ refuse him/ her to participate or withdraw from the study at any time. I understand that refusal to participate or withdrawal after initial consent will not affect my/ my child’s current and or future treatment. I also understand that declining or withdrawing from this genetic testing component will not affect my/my child’s participation in the main study titled [insert study title]. I have had the opportunity to ask questions and all my questions have been answered satisfactorily. I am aware that in the use of the use of this information, my identity will be concealed. 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. I will receive a copy of this signed consent form.

Name of Participant/ Participant’s Parent/ Guardian: ……………………………………………...

Signature of the Participant/ Participant’s Parent/ Guardian: ……………………………………...

Make a thumbprint in the box below *<< if the participant can’t sign>*

Date: *[DD/MM/YYYY]*

Name of Person Administering Consent: …………………………………………….....................

Position/ Title of Person Administering Consent: …………………………………………………

Signature of Person Administering Consent: ……………………………………............................

Date: *[DD/MM/YYYY]*

*\*If the participant is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant and that informed consent was freely given by the participant.*

Name ……………………………….. Signature of Witness ……………… Date ………………..