**FORM 7.1 F- TEMPLATE FOR INFORMED CONSENT FORM FOR GENETIC STUDIES**

**Informed Consent for Genetic testing**

**[Language]**

**[version number]**

**[version date]**

**[insert the tittle of the study]**

**INTRODUCTION**

*Your child is being invited to take part in a research study.  Before you decide on behalf of 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 your child to participate in this research.*

**A. Purpose**

The purpose of this consent form is to give you information so that you can decide whether you want your child to provide blood and health information for genetic research.

Your child’s participation in this genetic research isvoluntary. 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 form on behalf of your child authorizing the use and disclosure of your unidentifiable health information for this additional study.

**B. Introduction**

Cells in the human body contain genes composed of deoxyribonucleic acid (DNA). The genes contain key instructions for cell function and help determine the characteristics of each individual. Genetic research uses DNA samples to help understand how different individuals respond to *[ e.g. TB, e.t.c] drugs*. Some people have special genes that make some *drugs* not work as good as in other people. We want to see if this is also the case in Uganda and whether this is important in order to determine if *[TB]* treatment is successful.

**C. About This Research**

Your child’s sample may be stored for a long time but not longer than *10 years*. If we do not use the samples, the samples will be destroyed after 10 years. Your child’s health and medical information collected for the study will be retained. The DNA information obtained from your child’s blood sample will be used along with the other information collected from the main clinical trial in which your child is a participant, to study the differences in response to drugs that is generally seen in people with *HIV or other diseases* that are receiving *treatment of ……*

**D. Procedure**

If you agree to allow your child to participate, a blood sample will be collected from him/her and used to study the interaction between your child’s DNA and *HIV or other diseases* Treatment. This sample is in addition to any blood samples that will be drawn for the purpose of your child’s medical care.

**E. Risks**

There may be non-physical risks associated with taking part in this study, such as the risks associated with a breach of privacy or confidentiality. We believe that the risk of such improper disclosure of 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.

**F. Benefits**

There will be no direct benefit to your child as a result of his/her participation in the genetic research as these tests are currently not planned during the study. It is possible that 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]*,

**G. Withdrawal of Consent and Destruction of Samples**

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

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

**H. Confidentiality** The clinical study team at IDI will be the only people who will know your personal information (name, phone number, and address). The study team will replace your child’s personal information with a coded identification number when 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 your child.

**I. Questions/Information**

This study has been reviewed by the *Joint Clinical Research Centre, Institutional Review Board.* You may contact the chairman of the Research Ethics Committee if you have any questions regarding your child’s rights as a study participant at any time.

***[insert IRB chairperson contact] e.g.***

Dr. David Kateete

IDI REC Chairperson

IDI REC Office,

**Infectious Diseases Institute Building,**

**Near Mulago Hospital Complex**

Telephone (Office): 0312-307000; Mobile:

If you or your child have any questions regarding this sample collection or genetic research or if your child experiences an injury caused by the sample collection procedure, you should contact

*[Insert PI’s name/ contact]*

Infectious Diseases Institute,

Makerere University College of Health Sciences, Mulago Hospital Complex, Kampala

Email :

Telephone

The undersigned, hereafter known as *[insert name of study*] trial participant promises the following:

* The information in this genetic testing informed consent sheet and the written informed consent form was explained to me by the study physician and understood by me.
* All my questions were answered to my satisfaction.
* I agree to take part in possible future genetic studies under the conditions as described in this informed consent sheet
* I received a copy of the signed written informed consent form.
* I know that participation in this study is completely voluntary and that I may refuse to participate or withdraw from the study at any time and I still may be part of the main *[insert name of study*] trial.
* Refusal to participate or withdrawal after initial consent will not affect my current or future treatment.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant’s parent (printed) Signature of participant’s parent

make a thumbprint \* in the box below

**Date:** **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_**

Day Month Year

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Administering Consent (printed) Position/Title

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Administering Consent **Date:** **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Day Month Year

*\*If the patient 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 patient and that informed consent was freely given by the patient*.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Witnessing Consent (printed) Signature of Person Witnessing Consent

**Date:** **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_**

Day Month Year