**FORM 7.3 C-PARENTAL CONSENT FORM**

[Language]

[Version number]

[Version date]

[INSERT TITLE OF THE STUDY]

PARENTAL INFORMATION LEAFLET

Dear Madam or Sir,

Introduction

Your child is being invited to participate in a research study at the Infectious Diseases Institute (IDI). The name of the study is “insert name of the trial”. Researchers at IDI are interested in learning more about [provide a brief background of the study;]. This is study is being sponsored by [Insert the name of the sponsor and other collaborating partners <<IF APPLICABLE>>

Why is this study being done?

[provide appropriate details on the purpose of the study;].

How many people are participating in this study?

About [insert total number of participants e.g. 200 children] will participate in this study. Your child is being invited to take part in this study because he/she has both HIV and TB.

**Study Procedures**

Your child will have a total of 7 study visits [insert the appropriate number of visits] for this study. These visits are done on days that your child will be coming for his/her usual appointments,

**Visit 1 – Screening and enrolment**

Insert study procedures to be performed on this visit

**Visit 2 and 4 (week 2 and week 4)**

Insert study procedures to be performed on this visit

**Visits 5 (week 6):**

Insert study procedures to be performed on this visit

**Visit 6 (Week 8)**

Insert study procedures to be performed on this visit

**Visit 7 (Week 24)**

Insert study procedures to be performed on this visit

**How long will the study last?**

Your child will participate in this study for a total of 6 months [insert appropriate time frame for which the study will last]. Your child will be required to take his/her HIV medicines without missing any doses. Your child should not stop his/her HIV medicines but continue after completing his/her TB or any other disease related to the study] treatment and after the study is completed.

**What will happen to my samples?**

The sputum and blood samples provided by your child will be used to learn more about [insert name of the disease e.g. TB, KS] germs in patients with HIV. You will be asked to sign a separate consent form on behalf of your child if you agree to allow any left-over of his/her samples to be stored for a long time. A separate consent form will also be needed for genetic testing which will be performed on your child’s blood <<IF APPLICABLE>>. Your child can still participate in this study if you refuse genetic testing on his/her samples or if you refuse to allow the researchers to store his/her samples for a long time.

**Home visits follow-up.**

In case your child misses any of his/her study visits, we will call you to find out how your child is. A home visitor may come to see your child at your home to plan the next steps.

**Risks**

The main risks of taking part in the study include side effects [Insert potential side effects]. In case your child develops abdominal pain, yellow eyes or vomiting, please let us know because these may be signs that your liver has been affected by the drugs.

**Benefits**

There may not be any direct benefit to your child from being in this study. However, the results of these tests will be used to help us learn whether or not we can adjust doses of [TB, or any other diseases in question] drugs for the treatment of patients in the future and whether higher doses of rifampicin will affect the amount of HIV medicine in the blood.

**Costs**

Your child will not be required to pay any costs to be part of this study.

**Reimbursements/Compensation**

There are no costs to be paid to you for participate in this study. However, your child will be required to attend to the scheduled study visits where the study team is responsible for meeting the costs of transport for both you and your child during each the study visit. You will be given [insert amount of money to be reimbursed or any form of compensation e.g. 30,000 or a bar of soap] UGX compensation for transport costs for each of the study visits and for any other visits that are required by the study.

**Participant rights**

Participation in this study is entirely voluntary. You have the right to refuse your child from participating in this study and this decision will not affect his/her treatment at IDI in any way. If you choose to allow your child to participate in the study, he/she has the right to withdraw from the study at any time. Any research results obtained prior to your child’s withdrawal of consent may however be used and some data may have already been published.

**Research-related injury**

In case your child feels unwell, please feel free to contact the study team by telephone or come and meet us at the [IDI Mulago complex in room # or TB clinic]. We might perform more tests, depending how sick your child is. Your child will receive healthcare until complete cure and stabilization of a research related illness. If we refer your child to hospital for a research related illness, the cost of referral and management of the condition shall be paid by the study.

**Sharing the Results**

We plan to share the results of this research with you and the IDI after the study and the results will be published.

**Reasons why your child may be withdrawn from the study**

Your child may be removed from the study without your consent for the following reasons [Insert as many reasons as possible]:

If the study is stopped or canceled.

**Whom to contact**

This study has been approved by the Joint Clinic Research Centre – Research Ethics Committee (JCRC-REC). 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.

Dr. David Kateete

REC Chairperson

IDI REC Office,

Infectious Diseases Institute Building,

Near Mulago Hospital Complex

Telephone (Office): 0312-307000

**Alternatives to Participation**

If you choose not to allow you child to participate, your child will continue to receive his/her treatment as normal at the IDI. Neither his/her treatment present treatment nor his/her future treatment at IDI will be affected in any way by choosing not to participate in this study.

**Confidentiality**

All your child’s information will be kept private and confidential. Your child’s name or address or any other identifying information will not be shared with anyone outside the study. Codes will be used to replace your child’s name so that no one can directly identify him/her. All your child’s records from this study will be kept confidential by the investigators of this study. No information that personally identifies your child will be disclosed in any publications that arise as a result of this study.

**Questions about this study**

The study doctor or nurse will explain this study to you and your child. If you have any questions you may ask them now or any time during the study. You may contact also:

Insert the name of the PI

Infectious Diseases Institute,

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

Mobile :

Informed consent

By signing the Informed Consent Form you agree to your child’s participation in this study.

The undersigned, hereafter known as INSERT THE NAME OF THE STUDY e.g SAEFRIF, NADIA, participant agree to the following:

The information in the patient information 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 the “…..study” under the conditions as described in the patient information leaflet.

I received a copy of the patient information leaflet and a 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.

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