**FORM 7.1B- INFORMED CONSENT DOCUMENT TEMPLATE**

***[Language]***

***[Version number]***

***[Version date]***

***[INSERT TITLE OF THE STUDY]***

Dear Madam or Sir,

**Introduction**

You are 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] will participate in this study. You are being invited to take part in this study because you have both *HIV and TB.*

**Study Procedures**

You will have a total of ***7 study visits*** *[insert the appropriate number of visits]* for this study. These visits are done on days that you would be coming for your 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?**

You will participate in this study for a total of 6 *months [insert appropriate time frame for which the study will last].* You should take your *HIV* medicines without missing any doses. You should not stop your *HIV* medicines but continue after completing your *TB* *or any other disease related to the study]* treatment and after the study is completed. After the study you will continue your usual care at IDI clinic. [Please provide appropriate guidance on how the participant will return to the standard of care after completion of their study visits, <IF APPLICABLE> e. g *If you were on dolutegravir, you will start taking it once a day 2 weeks after you have completed your TB medicines, which is recommended by our Ugandan guidelines]*

**What will happen to my samples?**

The sputum and blood samples you provide 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 if you agree to allow any left-over 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 blood <<IF APPLICABLE>>. You can still participate in this study if you refuse genetic testing on your samples or if you refuse to allow the researchers to store your samples for a long time.

***Home visits follow-up.***

In case you miss any of your study visits, we will call you to find out how you are. A home visitor may come to see you 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 you develop 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 you 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

You 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, you will be required to attend to the scheduled study visits where the study team is responsible for meeting the costs of your transport 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 to participate in this study and this decision will not affect your treatment at IDI in any way. If you choose to participate in the study you have the right to withdraw from the study at any time. Any research resultsobtained prior to your withdrawal of consent may however be used and some data may have already been published.

**Research-related injury**

In case you feel 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 you are. You will receive healthcare until complete cure and stabilization of a research related illness. If we refer you 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 you may be withdrawn from the study**

You 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 *Infectious Diseases Institute Research Ethics Committee (IDI REC)*. You may contact the chairman of the Research Ethics Committee if you have any questions regarding your rights as a study participant at any time *(Insert the chair’s contacts)*

**Alternatives to Participation**

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

**Confidentiality**

All your information will be kept private and confidential. Your name or address or any other identifying information will not be shared with anyone outside the study. Codes will be used to replace your name so that no one can directly identify you. All your records from this study will be kept confidential by the investigators of this study. No information that personally identifies you 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. 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 participate 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 (printed) Signature of participant

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*.

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

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

Day Month Year