**FORM 7.1D- INFORMED CONSENT DOCUMENT TEMPLATE: TISSUE/BLOOD STORAGE FOR FUTURE USE**

**[Language]**

**[Version number]**

**[Version date]**

**[INSERT TITLE OF STUDY….]**

**INFORMED CONSENT FOR THE STORAGE OF BIOLOGICAL SPECIMENS**

**Introduction**

*Your child is being invited to take part in a research study.  Before you decide whether your child can participate in this study, 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 you wish to take part.*

**What is the purpose of the study?**

**Please insert the purpose of the study; e.*g. ... [****The purpose of this study is to understand the effect of a higher dose of one of the TB drugs (rifampicin) on HIV medicines, in particular efavirenz and dolutegravir.*

**Why store a specimen?**

*Start by listing the samples collected if more than one**and then write the rational for storing the sample*

**What quantity of my child’s sample will be stored?**

If you agree to storage of your child’s blood sample, 10 mL of *blood* will be taken every 2 weeks during the first 8 weeks of your *[HIV/AIDS /TB/ any other disease]* treatment, therefore, 60-70 mL of *blood* will be taken from your child for these purposes through-out the study period.

**Handling of stored samples**

Your child’s blood samples and sputum will be stored at the *Infectious Diseases Institute (IDI)* in Kampala and also at the *…...laboratory of Makerere University*, *or other laboratories located outside Uganda if applicable*

**How long will my child’s sample be kept?**

*Your child’s sample may be stored for a long time but not longer than 10 years*

**Will my child’s taking part in this study be kept confidential?**

Confidentiality will be maintained at all times.  All samples will be coded (but it will be possible to link results to anonymized data collected from this study). Once the study has been completed, we will ensure that no one can link your child’s identity to his/her clinical details.

**What policies will govern the use of my child’s sample in future research?**

Further approval will be sought from an accredited ethics committee for any future studies other than the one you are currently enrolled in. IDI will act as the guard of all the samples obtained as part of this project for research purposes. In some cases, with permission from an ethics committee; a small amount of your child’s sample will be provided to other researchers and may be sent to countries outside Uganda. [*Only if you plan to export samples to foreign countries]*

**Withdrawal of Consent and Destruction of Samples**

You may withdraw your parental consent to store your child’s sample without affecting his/her participation in the main *clinical trial or the main study.*

To withdraw your parental consent for storage of your child’s samples, you will contact the 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 storage during this time, you may request that your child’s blood *[include other categories of biological samples]* sample to be destroyed and no longer used in research. Any research resultsobtained prior to your parental withdrawal of consent will however be used.

**What are risks that may be associated with storage of your child’s sample?**

The other potential risk is loss of confidentiality. However, several measures have been put in place to ensure that your child’s information is not leaked to individuals who are not part of this research.

**What are the possible benefits of taking part?**

It is unlikely that the study will be of direct benefit to your child; however, it may benefit your child and other patients who on *[TB/ HIV AIDS/ or any other diseas*e] treatment in the future.

**Who is organizing and funding the research?**

This study is funded by the *[European and Developing Countries Clinical Trials Program (EDCTP). Write the appropriate organization]*

**Who has reviewed the study?**

This study has been reviewed by the *[Infectious Diseases Institute, Research Ethics Committee.]* 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 the contact for the chair)*

**Out of hour’s emergency contact**

For further information about this study, please contact: *[insert study Principal investigator’s name and contact]*

**Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.**

**Consent for storage and use in possible future research projects.**

I agree that the sample(s) *[outline the category of specimen e.g. blood, urine]* I give and the information gathered about me can be stored by The Infectious Diseases Institute as described in the attached information sheet. I understand that my data and sample(s) will be securely stored and be identified only by a code.

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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*.

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

**Date:** **\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_** Day Month Year