**[*Study institution name, logo, and address]***

## STUDY TITLE*:* Measuring the impact of [*country name*] program for prevention of mother-to-child transmission of HIV (PMTCT)

## INFORMED CONSENT FORM: LONG TERM SPECIMEN STORAGE AND FUTURE USE

**STUDY SITES:**

**Protocol Version \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PHONE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INTRODUCTION:**

You have decided to take part in the research study named above, being conducted by the [*study institution and collaborators*]. While you are in this study a blood sample (dried blood spot) may be collected from you and your baby for the laboratory tests mentioned in the consent form you signed to join this study. After those tests are done for this study, there may be some of your sample leftover. These samples may be useful for other research studies that have not yet been developed. This consent form gives you information about the collection, storage and future use of these samples and asks you for permission to do this. The study staff will talk to you about this information. Please ask if you have any questions. You will be asked to sign or make your mark on this form to indicate whether or not you agree to have your samples stored after this study has ended and used for future studies. You will be offered a copy of this form to keep.

**YOUR PARTICIPATION IS VOLUNTARY:**

Allowing your and/or your baby’s samples to be stored after this study has ended and used in the future is completely voluntary. You may decide not to have any samples stored other than what is needed to complete this study and still be in this research study or any future study.

Even if you decide now that your samples can be stored for future research, you may change your mind at any time. If this happens, you must tell the study staff that you have changed your mind. If you decide not to have your and/your baby’s samples stored and used for future research after this study has ended, any samples remaining in the study laboratory will be destroyed at the end of the study.

**PURPOSE:**

If you agree to have your and/or your baby’s samples stored after this study, your samples will be used for future research studies that have not been developed yet.

Your samples will not be sold or used directly to produce commercial products. Research studies that want to use your samples will be reviewed by the Sponsors’ Ethics Committee and a special committee at [*local institution*]. Only studies that are approved by both committees will go ahead.

**PROCEDURES:**

**Collection of samples for long term storage**

While you are in this study, your blood sample and/or your baby’s blood sample may be drawn from you and/or your baby today as mentioned in the consent form you signed to join the study. The amount of the blood sample drawn from you and/or your baby should be enough to finish the tests mentioned and check that the results are correct, but often there is some blood sample left over at the end of the study. It is this leftover sample that the researchers would like to keep after this study has ended. No extra blood sample will be drawn during this study specifically for long term storage.

The blood sample drawn from you and/or your baby will be tested for HIV infection. Part of the sample will be tested immediately for the tests mentioned in the consent form you signed to join this study, and the amount left over will be stored for future use.

**Long term storage of samples**

[*Name of principal investigator(s)*] will make sure that your blood sample or your baby’s blood sample will be stored safely and securely in a storage facility at [*name and address of laboratory*]. Only the people who work for the study, the laboratory and approved researchers will have access to your samples. The people who work at the facility will not have any information that identifies you. There is no limit on how long your samples will be stored there.

**Application to use the samples in storage**

In the future, any researcher who wants to use your samples for a new study must get approval from the [*name of study institution and principal investigator(s)].* The approved researchers may be given information about you such as your age and sex, but they will not be given your name or any other information that identifies you.

**Shipment of the samples to a laboratory outside of [*study country*]**

The future studies that are approved to use your samples may need to ship them to a laboratory outside of [*study country*] for tests. If that happens, only enough of the sample will be shipped to complete the tests required. Once those tests have been done and that study has ended, any samples left over in that laboratory will be destroyed or returned to [*study country*] to go back into long term storage.

**RISKS and/or DISCOMFORTS:**

There are risks related to storing your samples. When tests are done on the stored samples there is a rare but possible risk to your privacy. It is possible that if others found out information about you that is learned from tests (such as information about your genes) it could cause you problems with your family (having a family member learn about a disease that may be passed on in families or learning who is the true parent of a child) or problems getting a job.

**POTENTIAL BENEFITS:**

There are no immediate benefits to you from having your samples stored. You and others could benefit in the future from research done on your samples.

**CONFIDENTIALITY:**

To keep your information private, your samples will be labelled with a code that can only be traced back to your study clinic. Your name, where you live, and other personal information will be protected by [*name of principal investigator(s)*]. When researchers are given your stored samples, they will not be given your personal information. The results of future tests will not be included in your health records. Efforts will be made to keep your study records and test results confidential to the extent permitted by law. Any publication of this study will not use your name or identify you personally. However, your records may be reviewed by the sponsor of the future study, study staff, study monitors, the companies that make the drugs used in the new study, and the [*medicines control board of country*].

In addition to the efforts made by the study staff to keep your personal information confidential, an Oath of Confidentiality was signed by all our staff working in this study. This Oath requires study staff not to tell people who are not connected with this study, information about you or other study participants or any other information related to the study.

If you have any questions concerning this study or consent form beyond those answered by the investigator, including questions about the research, your rights as a research subject or research-related injuries; or if you feel that you have been treated unfairly and would like to talk to someone other than a member of the research team, please feel free to contact the [study institutions and sponsors] using the contact information below.

[*Insert names, addresses, and phone contacts of study institutions and sponsors here.]*

**SIGNATURE PAGE**

## *Measuring the impact of [country name] program for prevention of mother-to-child transmission of HIV (PMTCT)*

**LONG TERM SPECIMEN STORAGE AND FUTURE USE INFORMED CONSENT**

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide it will not affect whether you can be in the research study, or your routine health care [**Choose “Yes” or “No” for each statement by inserting your initials on the line].**

I agree to have samples of my blood sample stored in [*country*] after this study has ended and used for future testing.

 Yes \_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_ N/A\_\_\_\_\_\_\_

I agree to have samples of my baby’s blood sample stored in [*country*] after this study has ended and used for future testing.

 Yes \_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_ N/A\_\_\_\_\_\_\_\_

I agree to have my blood sample shipped to laboratories outside [*country*] for tests required for future studies that have been approved:

 Yes \_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_ N/A\_\_\_\_\_\_\_\_\_

I agree to have my baby’s blood sample shipped to laboratories outside [*country*] for tests required for future studies that have been approved:

 Yes \_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_ N/A\_\_\_\_\_\_\_\_\_\_\_

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Participant Name (print) Participant Signature or Mark Date

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

Study Staff Conducting Study Staff Signature Date

Consent Discussion (print)

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Witness Name (print) Witness Signature Date

(As appropriate)

YOU WILL BE OFFERED A COPY OF THIS CONSENT FORM TO KEEP.