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

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

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

**Household Survey: 18-24 month mothers/caregivers**

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

**What you should know about this research study:**

* We give you this consent so that you may read about the purpose, risks, and benefits of this research study.
* The main goal of research studies is to gain knowledge that may help future patients.
* This research will not directly benefit you or your child.
* You have the right to refuse to take part or refuse to allow your child to take part, or you can agree for you or your child to take part now and change your mind later.
* Whatever you decide, it will not affect your or your child’s regular care.
* Please review this consent form carefully. Ask any questions before you make a decision.
* Your participation and your choice to allow your child to participate are voluntary.

**Introduction**

I am atrained research staffwith [*study institution*] based in [*city*]. We are conducting a research study with [*study sponsors/collaborators*] to learn about a program to protect children in [*country*] from HIV infection. This study was reviewed and approved by the [*research boards/approving body*]. You and your child are invited to participate in this study because you live in [*country*] and are the mother or caregiver of a child who is or who would have been between 18 and 24 months of age.

This form tells you why the study is being done, who is being asked to participate, and what your participation will involve. Please read this form carefully. If you prefer, I can read the form to you. Afterwards, I will review a few key points with you and answer any questions you might have. If you are interested in participating in the study after reviewing this form, I will ask for your signature.

**Purpose:** This study is being done to learn more about how to protect children in [*country*] from HIV infection. Sometimes babies get HIV infection from their mothers, and [*country*] has a special program to help prevent this from happening. The study will see if the program is working to prevent HIV infection in babies and to help children in [*country*] live longer.

This study is being conducted in [*areas/regions of country*] in [*country*]. Households within these areas were selected at random.

**Procedures and Duration**

If you agree to participate in this study, you will be asked to do the following:

* Allow surveyors to collect GPS coordinates for your home using handheld GPS devices. This will allow us to collect accurate information about the location in which the survey is conducted.
* Complete a short survey that should take about 30-60 minutes to complete. You can identify a quiet and private place where we can complete the survey. The surveyor will ask questions about you and your baby including your use of health care, your pregnancy and birth history (only if you are the biological mother), your HIV testing history and status, and basic characteristics of your household. If your baby passed away, we will ask you about the possible causes of his/her death.
* Show yours and/or your child’s health card. This will allow us to collect accurate information about the medications you and your child received during your pregnancy, delivery, and after delivery.
* If you are the biological mother and do not know your HIV status or you are HIV negative, you will be tested for HIV during this visit using HIV rapid tests approved for use in [*country*]. You will receive the results of this HIV testing immediately (during the survey visit). If your HIV test result is positive, you will be asked to provide an additional blood sample (dried blood spot) for testing in a central laboratory in [*city*]. The survey assistant will clean your finger with a swab of alcohol, allow the cleaned area to dry, prick your finger with a small needle to produce small drops of blood, and collect a few blood drops on a piece of filter paper.
* If you are the biological mother and already know you have HIV infection, you will be asked to provide a dried blood spot sample for testing in a central laboratory in [*city*]. The survey assistant will clean your finger with a swab of alcohol, allow the cleaned area to dry, prick your finger with a small needle to produce small drops of blood, and collect a few blood drops on a piece of filter paper.

If your child is present and you consent to your child’s participation in the study, his/her involvement may also include the collection of a blood spot sample for HIV testing. This will involve cleaning the child’s heel with a swab of alcohol, allowing the cleaned area to dry, pricking the child’s heel with a small needle to produce small drops of blood that will be collected on a piece of filter paper.

Once collected, the filter paper(s) containing your and/or your child’s blood will be dried and then sent to the laboratory for HIV testing. The laboratory will destroy the blood samples according to standard biohazard procedures one year after the survey is completed.

Neither your child’s name nor your name will be associated with the blood sample provided by you or your child; instead, it will be identified with a unique code. However, if we do collect a dried blood spot sample for testing at the laboratory, we will ask for your name, date of birth, national ID number, and address so that we can provide you with the test results. You will be able to pick up the test results at your local clinic between 6-8 weeks after the survey is conducted. You will only be given your results if you show your national ID card (or other identifier) to the nurse. Your HIV test results will be sent to the clinic in a sealed envelope identified by your name, date of birth, and national ID number.

Study timing: The questionnaire should take about 30-60 minutes to complete. HIV testing and the collection of one dried blood spot sample should take no more than 15 minutes. The total participation time should be about one hour.

**Risks and Discomforts:** Some of the questions asked in the questionnaire may make you feel uncomfortable or embarrassed. Some questions may ask about children you may have had that have passed away, and these questions may cause you some sadness or discomfort. You are free to decline to answer any question or stop participating at any time. If you provide identifying information so that you can receive your HIV test results, there is a minimal risk of breach of confidentiality, which could result in unwanted disclosure of HIV status and associated potential distress; however, we are taking precautions to minimize this risk. If you wish to receive your HIV test results and/or your infants’ test results, you may find out for the first time that you are HIV-infected, which would result in emotional distress. Your HIV test results will be provided by the nurse at the local clinic, according to standard HIV testing and counseling guidelines in [*country*].

Your child may experience brief discomfort from the heel stick during the collection of the blood spots. Infections at the site of the heel stick are rare. Similarly, while the finger stick blood sample you provide might be uncomfortable, it is very unlikely to cause an infection. If you are currently pregnant, there is no increased risk to you from this procedure. We will not know the result of the dried blood spot tests immediately because they require analysis at the laboratory.

**Benefits**: There is no direct benefit to you or your child for participating in the study. However, this study will help the study team understand if a program in [country] to prevent HIV infection in babies is working. This is very important so that we know if the program is having the intended effect, or if there are ways that we can help to make the program work better.

**Compensation/ Payment**: We will provide you with a small gift as a thank you for your time. This will be in the form of a small household item valued at US$4.

**Confidentiality:** If you agree to participate in this study, we will ask you to sign and to provide your and your child’s names on this form. However, your and your child’s names will **not** be recorded on any other survey materials; instead these materials will be linked using a unique code. More specifically, we will **not** enter your name into the questionnaire database, on the filter paper on which we will collect your and/or your child’s blood, or on any other forms. We will make every effort to ensure that no one will know your answers to the questionnaire and your or your child’s HIV status based on the blood samples collected in this study.

So that you can receive the results of your or your child’s HIV test, we will ask you to provide us with your name, date of birth, national ID number and address. Once the HIV test results are available, we will link your test results with the unique code attributed to your blood sample, so that the nurse at your local clinic can provide you with your HIV test results between 6-8 weeks after you have taken part in the survey. Publications or presentations with results of this study will not include individual names or other personally identifiable information. The dataset containing identifying information will be password-protected and encrypted on each tablet used in the field, and will backed-up daily on Formhub ‘cloud’ storage, and will only be linked with the blood samples after the laboratory provides the HIV test results, to allow return of results to study participants.

All signed consent forms will be kept in a locked cabinet in a locked office, and only authorized study personnel, including personnel from the [*study institution/sponsors*], will have access to these records. The study database will be password protected so that only authorized study personnel have access to these records.

When the study is completed, the data may be saved for use in future research. Biospecimens collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. The study team will retain this study information for up to ten years after the study is over. The same measures described above will be taken to protect confidentiality of this study data.

**Costs of Study Participation**: There is no cost to you for participating in this study.

**Rights***: Participation in this study is completely voluntary.* You have the right to decline to participate or to withdraw at any point from this study without penalty or less of benefits to which you are otherwise entitled. Similarly, you can withdraw your child’s participation at any time.

**Questions**: Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

If you have any additional questions or concerns about this study, you can contact [*names and phone numbers of principle investigator and study coordinator*].

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.]*

 Please check this box if you agree to be contacted to participate in other studies being conducted by our research group. These additional studies are not part of the current study and checking this box does not obligate you to participate. These studies could involve surveys about your health or blood draws. You will be given details of any additional studies before agreeing to participate and asked to provide separate permission for them.

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

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

**Authorization for your participation**: You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above and have decided to participate.

Do you agree to participate in the questionnaire survey? Yes\_\_\_\_\_ No \_\_\_\_\_

Do you agree to provide a blood sample to determine HIV status? Yes\_\_\_\_\_ No \_\_\_\_\_ NA\_\_\_\_\_

Do you agree to receive the results of your HIV test? Yes\_\_\_\_\_ No \_\_\_\_\_ NA\_\_\_\_\_

**Authorization for your child’s participation:** You are making a decision whether or not to allow your child to participate in this study. Your signature indicates that you have read and understood the information provided above, and have decided to allow your child to participate. The date you sign this document to enroll your child in this study, that is, today’s date, MUST fall between the dates indicated on the approval stamp affixed to each page. These dates indicate that this form is valid when you enroll your child in the study but do not reflect how long your child may participate in the study. Each page of this Informed Consent Form is stamped to indicate the form’s validity as approved by [study institution].

Do you agree that your child participate in this study by providing a blood sample?

 Yes\_\_\_\_\_ No \_\_\_\_\_ NA\_\_\_\_\_

Do you agree to receive the results of your child’s HIV test? Yes\_\_\_\_\_ No \_\_\_\_\_ NA\_\_\_\_\_

Participant's Name *(please print)*

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

Participant's Signature Date

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

\*Infant Participant Name (*please print*)

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Witness’ Name *(please print)* Witness’ SignatureDate

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Witness’ Relationship to mother/caregiver

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Interviewer’s Name Date

**We will give you a copy of this consent form to keep for your records.**