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

**STANDARD OPERATING PROCEDURES**

**Chapter 1. INTRODUCTION**

We are conducting an impact evaluation of the national program for the prevention of mother to child transmission of HIV (PMTCT).

The main objectives are to find out how many children of HIV positive mothers are infected with HIV and how many are alive and not infected with HIV. Our study will provide feedback to the national program about the effectiveness of the PMTCT program. This manual outlines the procedures for the survey. All staff working on the survey must be familiar with this document and follow the survey procedures outlined below.

**Summary of survey procedures**

The household survey will be conducted between [*dates of study implementation*] in [*areas of country to be surveyed*]*.* The survey will be conducted using [number] teams, each consisting of one driver, one team leader and [number] data capturers. Eligible participants are all infants born 18 to 24 months prior to the survey date and their mothers or caregivers (called “mother-infant pairs”) who live in the selected enumerations areas to be covered by the survey. Only a pre-determined fraction of eligible mother-infant pairs and mothers will be invited to participate in the survey. We anticipate that on average we will enroll a total sample size of about [number] mother-infant pairs.

Teams will be assigned enumeration areas. Prior to starting the survey, the boundaries of each enumeration area will be explained to the team. A list of households with possible eligible mothers and infants will be compiled with the help of village health workers/ health promoters. A pre-determined fraction of eligible mothers and infants will be selected and data capturers will visit the households of selected mother-infant pairs, assess their eligibility, and invite them to participate in the survey. Each participating mother/caregiver will be asked to sign a consent form and answer a questionnaire. Finger prick blood samples will be collected from all living mothers for either home-based HIV testing (for mothers with unknown or negative HIV status) and/or confirmatory testing (for mothers with known HIV infection) . A heel/toe prick blood sample will be collected from living infants born 18 to 24 months prior to the survey date whose mothers have unknown or positive HIV status. [Each participating mother/caregiver will receive a small incentive for taking part in the survey].

More specifically, the survey will consist of the following procedures:

1. Individual questionnaires to be administered to all mothers/ caregivers of eligible infants (born 18-24 months prior to the survey date)
2. Finger-prick blood samples from all living mothers of eligible infants (born 18-24 months prior to the survey date)
3. Heel/toe-prick blood samples from all living infants born 18 to 24 months prior to the survey date whose mothers have unknown or positive HIV status. (Infants whose mothers test negative during the home-based HIV testing will not have a blood sample collected.)
4. Verbal autopsy questionnaires to be administered to caregivers if the mother of an infant born 18 to 24 months prior to the survey date is deceased
5. Verbal autopsy questionnaires to be administered to mothers of infants born 18 to 24 months prior to the survey date if the infant is deceased
6. GPS coordinates will be collected at all facilities and all households

**Chapter 2. BEFORE YOU LEAVE THE OFFICE**

The successful implementation of the survey is dependent on careful planning. It is very important that the team is properly prepared and equipped before they go out in the field. Every piece of equipment you take out has an important function and it is critical that nothing is forgotten. For this reason checklists have been devised which detail each piece of required equipment. Each item will be signed out of the office and then signed back in on the team’s return. All supplies are carried out into the field using storage trunks. The *Check In Form* lists everything that you will need to take from the office before you leave for the field; quantities are per team/per trip.

**Chapter 3. SETTING UP IN AN ENUMERATION AREA (EA)**

**Mapping the Enumeration Area**

In each selected enumeration area, the survey team will establish:

* Key landmarks that outline the EA;
* The names and description of key households that demarcate the EA; and
* The names of *all* villages located within the EA.

The team leader will work with community health workers (CHW) to conduct a full census in each selected EA (see CHW Mapping SOP).

**Identifying Potentially Eligible Households**

The team leader will provide you with the *Selected Mothers and Infants* List, which will detail households where an infant was born in the three years prior to the survey, including the households where the mother and/or the baby are no longer alive. This list will be put together based on information from CHW/health promoters and will detail the households that have an eligible mother-infant pair, as well as the specific mother-infant pairs in each household that have been selected for screening.

As discussed in detail below, the data capturer will conduct the following procedures:

Households with mother-infant pairs selected for screening will be visited, screened using the *Screening Form* (and the *Eligible Infants Chart*). A numbered ‘PMTCT Survey’ sticker will be placed on all the screened households. Eligible mother-infant pairs where both the mother and the infant are dead will be recorded on the *Deceased Infant and Deceased Mother Form*. Eligible infants (born 18-24 months prior to the survey date) whose mothers are 14 years old or under will be recorded on the *Ineligible Mothers Form*. Eligible 18-24 month mother-infant pairs where the infant and/or the mother are alive will be recorded on the *Registration Form*. For the selected mother-infant pairs, the data capturer will fill in the columns of the *Registration Form* while completing the various stages of the survey:

1. informed consent process (and signing the *Consent Form*);
2. administering the questionnaire using a tablet;
3. collection of finger prick blood sample from the mother and heel prick sample from infants born 18 to 24 months prior to the survey date (as well as filling in the *Lab Request Form* and collecting identifying information from mothers/ caregivers for test result return).

Before starting to screen selected mother-infant pairs, the data capturers should ensure that all the necessary forms are in order and ready to use, so that the potential participant is not kept waiting for the data capturer to find the forms/other materials needed.

**Chapter 4. SCREENING ELIGIBLE PARTICIPANTS**

Materials:

* *Selected Mothers and Infants List*
* *Screening Form*
* *Eligible Infants Form*
* *Ineligible Mothers Form*

The data capturer will visit all households listed on the *Selected Mothers and Infants List*.

A selected 18-24 month mother-infant pair is eligible to participate in the survey if the infant was **born 18 to 24 months prior** to the survey date (whether alive or deceased); the mothers and caregivers of these babies are **15 years old or above;**

A caregiver of an eligible child may be someone caring for the child because i) the mother has passed away, ii) the mother has left the baby for a prolonged period of time (e.g. the mother is way from the household for the entire period the survey team is in that village/area), or iii) the mother is away for a prolonged period of time. If the mother is away at work and has left the child in someone else’s care for the day, that person does not constitute a ‘caregiver’ according to the definition of this study; in that situation you need to come back to the household when the child’s mother is at home. The only exception to this rule is if the biological father of a living, eligible infant is available and the mother will be away from the household for the *entire period the survey team is in that village/ area*. In this instance, he can participate in the survey as a caregiver; he must be 15 years old or above to participate and his age should be recorded on the *Registration Form* (as for any other caregiver).

**How to complete the Screening Form**

The Screening Form has 2 main sections: 1) the top of the form (date, team number, name of data capturer, village, district, province, number of selected 18-24 month M-I pairs for that household); 2) instructions, in terms of the questions to ask and how to assess the eligibility of each household.

Before arriving at the household of interest, the data capturer should fill in the date, team number, name of data capturer, village, enumeration area, district, and province.

Approaching Household Heads

Upon approaching a household, the data capturer will greet household members and request to speak with the household head. If the household head is not available, request to speak with an adult. If the household head has agreed to speak with you, convey the following information:

*Hello. My name is* *­­­­\_\_\_\_\_\_. I am a trained researcher with* *[study institution] based in [city]. We are conducting a research study with the [study sponsors/collaborators] to learn about a program to protect children in [country] from HIV infection. A community health worker working with [study institution] previously visited your household and determined that there were eligible mothers or children in your household for participation in our study. I would like to ask you a few questions about the people who live in your household similar to the questions you were previously asked to confirm that there is a mother and child in your household that is eligible to participate in our study. We will only conduct this survey in some households in your community and in those households only some women and children are invited to participate.*

In each household, you will only ask the household head about the mothers and infants that have been selected in the household. Use the *Selected Mothers and Infants List* to ask the household head the following questions from the *Screening Form:*

1. *Is \_\_\_\_\_\_\_ (Initials of Selected Infant) a child in this household born in the past 2 years?* Instructions to the Data Capturer: Ask the birthdate of the selected infant born in the past 2 years and check against the ELIGIBLE INFANTS FORM.
2. *I know this can be sensitive, but please do your best to remember. Was \_\_\_\_\_\_ (Initials of Selected Infant) a child in this household born in the past 2 years who was stillborn or is no longer alive?*Instruction to the Data Capturer: Ask the birthdate of the selected infant born in the past 2 years (stillborn or deceased) and check against the ELIGIBLE INFANTS FORM.
3. Is \_\_\_\_\_\_\_ (Initials of Selected Mother/Caregiver of the Selected Infant) **at least 15 years** of age?

How to use the Eligible Infants Form

The *Eligible Infants Form* indicates whether a 18-24 month mother-infant pair is eligible to participate in the survey. The form will produce one of the following messages:

* ELIGIBLE 9-18 month mother-infant pair
* INELIGIBLE 9-18 month mother-infant pair

If a 18-24 month mother-infant pair is eligible, the selected infant was born in the past 18-24 months. Fill in the rows corresponding to that household according to the answers provided by circling either ‘Yes’ or ‘No’ for each of the three questions (‘Questions’ column). Establish whether the selected mother-infant pairs are eligible based on these answers.

A selected 18-24 month mother-infant pair is eligible if the household head answered ‘Yes’ to *either* the first or the second question, the infant was born in the past **18-24 months** (as determined by the *Eligible Infants Form*, AND the household head answered ‘Yes’ to the last question (meaning the mother or caregiver is 15 years old or above).

Write the result of this assessment under the ‘Eligible HH?’ for the corresponding household, by circling ‘Yes’ if the household is eligible or ‘No’ if ineligible.

For other possible scenarios, fill in the appropriate code in the ‘Other’ row: 1 “No competent household member present”, 2 “No one at home”, 3 “Abandoned household”, 4 “Refused to answer to screening form”.

* If no one was at home, the data capturer should re-visit the household later in the day or the following day. For this purpose, make a description of the household on the back of the *Screening Form*; for example “a household with six huts near a big mopane tree by the road to the river”. This description should be detailed enough to allow anyone else to identify the household during a follow-up visit.
* Survey members will come across some houses that look abandoned. Usually the front yard has not been well kept, the doors are locked, the roofing material is blown away, no one is around. Survey members should confirm this status with neighbours before deciding that the household is abandoned and filling in the *Screening Form* accordingly.

After filling in the *Screening Form*, request the household head to allow you to place a sticker on one of the exterior walls of his/her house. If allowed, take a ‘PMTCT Survey’ sticker and write on it the household number that you allocated to the household and wrote on the top of the *Screening Form*. Place this sticker on a wall of the household. All households screened for the survey should have a numbered ‘PMTCT Survey’ sticker placed on their walls, irrespective of the presence of eligible mother-infant pairs or mothers or presence of household members. Request to keep this sticker on their house for the next few weeks as it is possible that some external monitors will be visiting them. If the household head refuses to allow you to place a sticker comment note this on the back of the screening form. This team will simply conduct a random check and will ask them a series of similar questions about the composition of the household; they will not be asked to participate in any survey at that time.

If none of the selected mothers/infants in the household are eligible, thank the household head and go to the next household that has a selected mother/infant (remember to number sequentially). If the household has at least one eligible selected infant whose mother/caregiver is 14 years or younger, record these infants on the *Ineligible Mothers Form*. If the household has at least one eligible selected infant whose mother/caregiver is 15 years old or above, request the household head to introduce you to the mother(s) and/or caregiver(s) of these children, and then start filling in the *Registration form*.

**How to complete the Ineligible Mothers Form**

Only fill in this form if you encounter a selected eligible infant whose mother/caregiver is 14 years old or under. Start a new form in each enumeration area. Fill in the top part of the form: team number, name of data capturer, enumeration area, and province. The data capturer should fill in one row for each selected eligible infant whose mother/caregiver is 14 years old or below. For each infant, fill in the following information:

* Name of the village
* Survey date
* Infant’s birth date - check that s/he is indeed eligible using the *Eligible Infant Form*
* Whether the baby is deceased – write “Yes” if the baby is deceased and “No” if alive
* Whether the data capturer talked to the mother or the caregiver – write “M” for mother and “C” for caregiver
* Mother’s age – ask the mother or caregiver her age in completed years.

If the age of the mother/caregiver written on this form is 15 years or above, information about the respective mother-infant pair should be recorded on the *Registration Form*.

**Chapter 5. ENROLLING ELIGIBLE PARTICIPANTS IN THE STUDY**

Materials:

* *Registration Form*
* *Instructions to Fill in the Registration Form*
* *Deceased Infant and Deceased Mother Form*
* *Eligible Infants Form*
* *Consent Form* (in all relevant languages)
* Label envelopes

Once the data capturer established that a selected mother-infant pair is eligible, he/she should proceed with recording their information on the *Registration Form.* Only mother-infant pairs in which at least the mother OR the infant is alive should be recorded on the *Registration Form.* However, if BOTH the mother and the infant are deceased at the time of the survey, information about them should be recorded on the *Deceased Infant and Deceased Mother Form*.

**How to complete the Deceased Infant and Deceased Mother Form**

The data capturers should start a new form in every enumeration area. The form should only be filled in for eligible 18-24 month mother-infant pairs where *both the mother and the infant are deceased* (as indicated in the title of the form). For every eligible mother-infant pairthe data capturer should fill in a single row.

Start by filling in the top part of the form: team number, name of data capturer, enumeration area, and province. For each mother-infant pair (meaning on each row) write:

**Village:** The name of the village where the eligible mother and infant have lived.

**Date**: The date when the DC visited the household of the eligible mother-infant pair.

**Infant birth date**: *Ask the household member: “When was this baby born? (the exact date)”*

Write the infant’s date of birth in the format indicated on the form: dd/mm/yyyy. To be eligible, the infant must have been born 18 to 24 months prior to the interview date (even if the infant was born dead). Check the eligible birthdays for each survey month using the *Eligible Infants Form* (see instructions on how to use this form above).

**Deceased Infant**: *Ask the household member: “I know it may be difficult to talk about this, but can you please tell me if this baby is no longer alive?”* Write ‘Yes’ if the eligible infant is deceased and ‘No’ if the eligible infant is alive.

**Deceased Mother**: *Ask the household member: “I know it may be difficult to talk about this, but can you please tell me if the mother of this baby is no longer alive?”* Write ‘Yes’ if the eligible mother is deceased and ‘No’ if the mother is alive.

If either the infant or the mother are alive and therefore the data capturer wrote ‘No’ for either of the two last columns of this form, information about this mother-infant pair or mother should be collected on the *Registration Form*.

It is extremely important that all mother-infant pairs that have been selected are screened, that their screening is conducted as outlined above, and that no mother-infant pairs or mothers that have not been selected are screened. These guidelines are the result of the assumptions used in calculating the sample size for the survey, so disregarding these guidelines would substantially undermine the study’s ability to collect accurate estimates.

**How to complete the Registration Form**

Before approaching a potentially eligible household, data capturers should complete the top section of the *Registration Form* including: date of visit, team number, name of data capturer completing the form, province, district, enumeration area and village name. The data capturers should start a new form every day and for each village. In other words, if you are covering two different villages in the same day you should start a new form (and re-start the count from 1) for each village. Similarly, if you’re covering a village over two days, start a new form (and re-start the count from 1) every day. The form should only be filled in for eligible mother-infant pairs if at least the mother OR the infant are alive. For every eligible mother-infant pair or motherthe data capturer should fill in a single row.

Data capturers will visit all the households with selected mother-infant pairs, administer the *Screening Form* and thus establish the eligible mother-infant pairs, and record information about all eligible mother-infant pairs on the *Registration Form.*

**How to fill in the first half of the Registration Form**

Ideally, the data capturers should fill in the first six columns of the *Registration Form* based on information provided by the mother/ caregiver of the eligible child. However, if the mother/ caregiver is not at home, another household member - an adult knowledgeable of the situation of the mother and her baby - can provide this information. This is important in order to ensure the enumeration of all eligible mother-infant pairs and random selection of a fraction of infants for the survey.

**HH no**: Record the household number in the first column of the form. This is the same number you allocated to each household on the *Screening Form* and wrote on the ‘PMTCT Survey’ sticker.

**Eligibility:** Indicate if a 18-24 month mother-infant pair. This is the same eligibility recorded on the *Screening Form.*

**Infant birth date**: *Ask the mother/caregiver: “When was your baby born? (the exact date)”* Write the infant’s date of birth in the format indicated on the form: dd/mm/yyyy. This is the main information establishing eligibility of the mother-infant pair, so listen, record and check this information carefully. If ‘*Eligibility’=*18-24 month mother-infant pair, the infant must have been born 18-24 months prior to the interview date to be eligible (even if the infant was stillborn).

**Infant alive**: *Ask the mother/ caregiver: “I know it may be difficult to talk about this, but can you please tell me if your baby is no longer alive?”* Circle ‘Yes’ if the eligible infant is alive and ‘No’ if the eligible infant is deceased. Mothers of both living and deceased infants (born 18-24 months prior to the interview date) are eligible to participate. Mothers of infants born 18 to 24 months prior to the survey date will be asked different questions depending on whether the infant is alive or deceased, hence it is extremely important to record this information accurately. Of note, if the infant is deceased and only the former caregiver of the child is available because the mother is also deceased, information about this mother-infant pair or mother should be collected on the *Deceased Infant and Deceased Mother Form* (explained above).

In the two above-mentioned columns you recoded information about eligible infants. Now you will start recording information about their mothers or caregivers.

**Mother/caregiver no**: *Ask each mother/caregiver with an eligible infant: “Are you this child’s biological mother?”* If ‘Yes’, the woman is considered the mother. If not, the woman/man is considered a caregiver.You may identify more than one eligible mother/ caregiver in the same household. To record this, identify a mother by the letter ‘M’ and a caregiver by the letter ‘C’, followed by the mother or caregiver’s number within the respective household (in the order you talk to them). Do NOT write the mother/ caregiver’s name on this form. For example, if in the same household there are 3 mothers and 2 caregivers, each with one eligible infant you should fill in 5 rows and write M1, M2, M3, C1, C2 in this column.

**Mother/caregiver age**: *Ask the mother/caregiver: “How old are you? (in completed years)”* Write the mother or caregiver’s age at her/his last birthday. S/he must be 15 years old or above to participate.If 14 years old or below, her children are not eligible to participate in the survey. In this case, you should record information about that mother/caregiver and her baby on the *Ineligible Mothers Form* (explained above).

If the data capturer is male and for any of the selected mother-infant pairs only the caregiver is available and the caregiver is a woman, contact your team leader, who will assign a female data capturer to interview the respective mother/caregiver. Such situations will not happen very often, but when they do it is imperative that a female data capturer interviews the caregivers, as the questionnaire for caregivers contains sensitive questions. Similarly, if the caregiver is a man, a male data capturer should interview him.

**How to fill in the second half of the Registration Form**

This information will be filled in as other survey procedures are being completed:

* Consent: after the completion of the informed consent process
* Registration: after and only if the mother/caregiver agreed to participate in the study
* Tablet: before administering the questionnaire
* Blood sample: after collecting the blood samples from the mother and/or the infant

First, if the woman has more than one eligible child it is important to make sure both of you are clear which of the infants is enrolled in the study. Once this information is confirmed, discuss in detail the survey, obtain informed consent to participate in the study (more details below), and continue to fill in the *Registration Form* starting with the seventh column.

**Consent Q**: Has the mother/caregiver consented to participate in the questionnaire survey? Circle ‘Yes’ or ‘No’ as appropriate. This information should be consistent with the consent form signed by the mother/ caregiver.

**Consent mother DBS**: Has the mother consented to provide a dried blood spot (DBS)? Circle ‘Yes’ or ‘No’ as appropriate. If only the caregiver is available (see ‘Mother/caregiver no’ column for the same row), s/he is not requested to provide a blood sample; in this case, circle NA (not applicable).

**Consent infant DBS**: For infants born 18-24 months prior to the survey date, has the mother/caregiver consented to infant DBS? Circle ‘Yes’ or ‘No’ as appropriate. If the infant is deceased (see ‘Infant alive’ column for the same row), circle NA.

**Consent mother DBS Storage:** Has the mother consented to storage of her DBS? Cross ‘Yes’ or ‘No’ as appropriate. If only the caregiver is available, she is not requested to provide a blood sample, in this case cross NA ( not applicable)

**Consent infant DBS Storage:** has the mother/caregiver consented to storage of her infants DBS? Cross ‘Yes’ or ‘No’ as appropriate.

If the mother/ caregiver refuses to participate in ALL components of the study (questionnaire, mother’s DBS, infant DBS), thank her for her time and proceed to the next household of a selected mother-infant pair. If the mother/caregiver agrees to participate in at least one study component, proceed with the survey and filling in the *Registration Form*.

**Registration**: Open a *new labels envelope* and add a WHITE ‘*mother barcode label’* in this column only if the mother/caregiver has consented to at least one of three components of the study (questionnaire, mother DBS, or infant DBS). A label envelope will contain 6 copies of a unique ‘mother barcode label’. For 18-24 month mother-infant pairs, label envelopes will also contain 5 copies of a unique ‘infant barcode label’. The ‘mother labels’ will be WHITE and the unique number will have the format ‘EMPxxxxx’ for mothers in 18-24 month M-I pairs (for example EMP00129, where the ‘E’ stands for ‘Endline’, ‘M’ for ‘Mother’, and ‘P’ for ‘Pair’). The ‘infant labels’ will be YELLOW and the unique number will have the format ‘EBPxxxxx’ (for example EBP02561, where the ‘B’ stands for ‘Baby’ and ‘P’ stands for ‘Pair’).

The data capturer will add labels from the same labels envelope on the *Lab Request Forms* and filter papers, and will enter the same study ID in the tablet for the corresponding mother/ caregiver. Even if the mother agrees to participate in all the components of the study, there will still be 1 ‘mother barcode label’ and, if applicable, 1 ‘infant barcode label’ left in the envelope for unexpected situations (dropping/ losing a label, other).

Each team will be allocated a range of study IDs:

* + Team 1: EMP00001-EMP02999 and the corresponding infant labels, and

EM20001-EM22999

* + Team 2: EMP03000-EMP05999 and the corresponding infant labels, and

EM23000-EM25999

* + Team 3: EMP06000-EMP08999 and the corresponding infant labels and

EM26000-EM28999

* + Team 4: EMP09000-EMP11999 and the corresponding infant labels and

EM29000-EM31999

Make sure you always use the labels within the range allocated to your team.

**Tablet no**: Following registration and prior to administering the questionnaire, write the number of the tablet used for the corresponding questionnaire. Each data capturer will use a different tablet.

**Verbal autopsy Mother**: For 18-24 month mother-infant pairs, have you administered the *Mother’s Verbal Autopsy*? (discussed in the next chapter) Circle ‘Yes’ or ‘No’ as appropriate. If the mother is alive, circle ‘NA’.

**Verbal autopsy Infant**: For 18-24 month mother-infant pairs, have you administered the *Infant’s Verbal Autopsy*? (discussed in the next chapter) Circle ‘Yes’ or ‘No’ as appropriate. If the infant is alive, circle ‘NA’.

**Blood sample mother**: Fill in this column after collecting DBS from the mother. Circle ‘Yes’ or ‘No’ as appropriate. If only the caregiver is available (see ‘Mother/ caregiver no’ column for the same row) OR the mother did not consent to the blood sample, circle NA.

**Blood sample infant**: Fill in this column after collecting DBS from the infant. Circle ‘Yes’ or ‘No’ as appropriate. If the infant is deceased (see ‘Infant Alive’ column for the same row) OR the mother/caregiver did not consent to the infant’s blood sample, circle NA.

While in the field, please refer to the *Instructions to Fill in the Registration Form* for a summary of the instructions to complete this form**.**

**How to obtain Informed Consent**

Once you selected an eligible mother-infant pair to participate in the study, proceed by explaining the study in detail and obtaining informed consent.

* Hand the mother/caregiver the appropriate consent form and ask if she would like to read the consent form or if she wants you to read it to her. If the mother/ aregiver indicates that she cannot read, request her to identify someone who can be a witness to this process. The witness must be over 18 years old and able to sign his/her own name. If she wants the information read to her, start reading her the form. If she would like to read it on her own, give her the form and let her read it.
* After reading the form, the data capturer should start by asking the participant to summarize in her own words what her participation in the study would entail. If she cannot fully answer how she will participate in the survey, the data capturer needs to go through the form with her again. Answering ‘this is research about health’ is notsufficient; participants must be able to outline what will happen to them and why (for example, ‘you will ask me questions about my baby and you will take my blood and that of my baby and test it for HIV’).
* Eligible mothers/caregivers must also understand the concept of anonymity. More specifically, they should understand that the *Registration Form*, questionnaire, and blood samples will be marked with a matching ID label to allow these items to be linked, but as these will not be linked to their name taken on the consent form, it WILL NOT be possible to link any information to their name. This means that we cannot give them or anyone else data from their specific questionnaire.
* The data capturer should explain to each participant that their and/or their baby’s HIV test results will be sent to the local clinic. Of note, they must agree to receive HIV test results (for both themselves and their infant), so they will have to provide identifying information so that staff at the local clinic can check their identity prior to disclosing their test results. For these participants, the data they provide is not anonymous; however, their identifying information will be stored in a password-protected database separate from the questionnaires and the HIV test results, and only authorized research staff will have access to it.
* If the data capturer feels that the she does not fully understand some concept of the study s/he must endeavour to explain this in greater detail until confident of the participant’s understanding.
* If it becomes clear during the summary process that the participant is unable to process what they read, then the survey team member should go through the consent form with them paragraph by paragraph; this should be done in a way that is not condescending.
* The eligible participant should then be given the opportunity to ask any questions they might have.
* The data capturer should mention that during the interview s/he would ask to see the mother and infant’s health cards. This is necessary to collect accurate information about the medications given to the mother and/or the baby. It is important that the data capturer mentions this during the informed consent form process, so that the participant is not surprised when asked to show the cards during the interview.
* After the data capturer is confident that the participant is clear about the study procedures, two copies of the consent form should be signed by the mother/caregiver. In order to ensure completeness, legibility, and that informed consent has taken place, the data capturer should complete both forms. In other words, the data capturer will mark all the relevant boxes with an ‘X’, print and sign their name, and date the form. The eligible participant should *only* print and sign their name and that of their eligible baby. If not literate, have the witness print the participant’s name and the participant put his/her mark. Have the witness print and sign their name underneath and state their relationship to the participant. After the consent forms are complete, one copy will go to the participant, and the survey team will file the second copy.
* The participant needs to sign the consent form; initials cannot be used instead. If this happens on the first form, tear it up and start again. If the participant does not have a formal signature, then s/he must put their full name on the signature line. Print and sign your name CLEARLY on the last line of the consent form. Even though you will do it a lot, don’t rush it. Enter the current date.

If the mother/caregiver refuses to participate, write the reason for refusal on the back of the Registration form. For example, possible reasons for refusal may be ‘Religious reasons’, ‘Husband not home to give permission’, ‘Family not here to give permission’, or ‘She doesn’t want to participate’.

* If they are reluctant to participate in the survey, and feel that somebody else could be found to replace them (another mother in the household or a neighbour), explain to them that the area where their house is has been chosen for this study and that some mothers/caregivers of infants born within certain dates who currently live in that area need to be recruited. If they do not agree to participate unfortunately it will not be possible to replace them with somebody else. Never force a person to participate in the survey if they really do not want to.
* If they do not want to participate because they do not have time, try to see whether it would be possible to come back later that day or the next day at a more suitable time and note these details on the back of the *Registration Form*, as follows: ‘Come back today at \_\_\_ time’ OR ‘Come back tomorrow at \_\_\_ time’ OR ‘Come back 2 days+ later’. If the data capturer wrote ‘Come back tomorrow at \_\_\_ time’ and it is the first day spent in that catchment area s/he should advise with the team leader if it would be possible to return the following day (depending on the time of the day when the eligible individual is expected to return). If the data capturer wrote ‘Come back 2 days+ later’ it will not be possible to enrol that eligible mother-infant pair in the study and these individuals should be marked as ‘Not available’.
* If the mother or caregiver is unsure about participating or wants to consult with anyone else (her husband or other household member), tell her you will come back to her house later and explain the study in more detail. Encourage her to take her time in deciding whether she wants to participate in the study.
* If an eligible mother/caregiver is not at home at the time of the first visit or tells you that she will have to leave the house in the following hours, write down on the back of the form the details of when it will be convenient to come back to enroll her in the study (based on the information she provides or from her household members).
* If the mother/caregiver refuses to participate in the survey, thank her for her time and go to the next household with a selected baby born in the previous 2 years.

**Chapter 6. ADMINISTERING THE QUESTIONNAIRE**

Materials:

* Tablet

As previously mentioned, male data capturers should speak to male *caregivers,* and female data capturers should speak to female *caregivers*. If the respondent is the biological mother, the interviewer can be either male or female.

Each data capturer will have one tablet with him/her. If the mother/caregiver has accepted to participate in the questionnaire component of the survey, and after you have chosen an appropriate place for the interview, turn on the tablet and log into the questionnaire.

**How to administer the questionnaire using a tablet**

You can access the questionnaire by pressing on the ‘ODK Collect’ icon on the tablet screen.

* Tap on ‘Fill Blank Form’ to start a new questionnaire
* Tap on the file corresponding to the questionnaire and enter the language of the interview.
* Enter the study ID for the respective mother/caregiver. Copy the study ID from the label you have just added to the *Registration Form* (the WHITE ‘mother barcode label’). The mother’s study ID will either have the format ‘EMPxxxxx’ or ‘EMxxxxx’. Use the keypad at the bottom of the screen to tap on the numbers and letters that you need.
* You will be asked five questions you can answer based on the information you collected on the *Registration Form* for the participant: the infant’s birth date, the mother’s age, whether the infant is alive or not, whether the respondent is the biological mother or the caregiver, and the mother/caregiver’s sex which can be observed. Do not ask this information again, as the participant already provided this information. Take great care in entering this information in the tablet, as participants are asked very different questions depending on whether they are biological mothers or caregivers, and on whether their infants are alive or deceased. An incorrect answer to any of these initial questions will result in completely non-applicable questions and potentially uncomfortable situations for the participant (for example, a caregiver being asked questions about her pregnancy with the child, or a mother of a deceased infant being asked questions about current breastfeeding practices). Out of concern for this issue, after you enter whether the infant is alive or not, and whether the respondent is the biological mother or the caregiver, you will be asked to confirm the information you entered before you can proceed with the questionnaire.
* Following these initial questions addressed to you, you can start addressing the mother/ caregiver and ask questions. There are three main type of questions: i) questions for which only one answer can be chosen, ii) questions for which the participant can choose more than one answer, and iii) questions for which you need to use the number pad and enter a number. Each question will have an instruction indicating how to answer the question - option (i), (ii), or (iii).
* Take the time in asking questions. While you will be reading these questionnaires many times and get used to its content, each participant will be hearing these questions for the first time. While you administer the questionnaire, if the participant did not hear or understand a question, do not rephrase the question and try to explain, simply repeat the question listed on the screen. If you explain or rephrase the question, it is possible that you may inadvertently change its meaning; it is very important that does not happen, as every participant has to be asked the same questions in order to compare their responses.
* During the questionnaire, you will ask to see the mother and infant’s health cards. If the mother/ caregiver agrees to show the health cards, make sure you inspect the cards for any of the questions you are instructed to do so. Be thorough in examining the cards.
* While administering the questionnaire you will notice a number of questions mentioning various HIV medications (e.g., tenofovir (TDF), lamivudine (3TC), dolutegravir (DTG), efavirenz (EFV), etc.) and prophylaxis drugs (e.g., AZT (zidovudine), NVP (nevirapine – available as tablets for adults and syrup for infants), CTX (Cotrimoxazole)). HIV positive mothers may know them by one of these names, so get familiar with these terms. You will show laminated pictures of each drug to participants for each respective question.

**How to complete the Verbal Autopsies (only for 18-24 month mother-infant pairs)**

When interviewing a mother in a 18-24 month mother-infant pair whose infant has died, the questionnaire might include some questions asking about the diseases and symptoms experienced by the baby before his/her death. Similarly, when interviewing a caregiver in a 18-24 month mother-infant pair and the biological mother is deceased, the questionnaire might include some questions asking about the diseases and symptoms she experienced before her death.

After you administer the questionnaire, check the *Registration Form* to remind yourself whether the participant agreed to the blood sample for herself and/or her baby. If the participant agreed to specimen collection, proceed with this procedure (see next chapter); otherwise thank the mother/ caregiver for her participation and provide her with the incentives.

* For all study participants, before completing the questionnaire you will be prompted to collect the GPS coordinates of the household. You may not be permitted to proceed with the rest of the questionnaire until GPS coordinates are collected. Ask for permission to step outside and collect GPS coordinatewhile standing at the **front door/entrance of the household** using the following procedures:

1. Take tablet to a location where you have a clear view of the sky (**Very important)**
2. When prompted, press the “Start GeoPoint” button
3. You will receive a message: “Loading location. Please wait. This should take a few minutes”. Do **NOT** press anything.
4. You will receive a message “Using GPS. Accuracy is \_\_\_\_m”. Do **NOT** press anything.
5. The latitude, longitude, altitude, and accuracy will appear and will automatically be recording on the tablet device.

Note:

* The GPS coordinates will be recorded in the tablet memory. You do **NOT** need to record the GPS coordinates on any forms.
* The GPS coordinates will load faster when the sky is clear and a bit slower when the sky is cloudy.

**Chapter 7. SPECIMEN COLLECTION**

Materials:

* 2 chairs (1 for data capturer, 1 for participant) (if possible)
* Bench or table (if possible)
* Paper towels
* Biohazard garbage bags
* *Lab Request Form*
* Lancets
* Sharps bin
* Alcohol swab
* Cotton
* Plastic bags for dried filter paper with filter paper and desiccant
* Tablet
* Drying boxes
* Sanitizer

**How to fill in the Lab Request Form**

Start a new form in each enumeration area, and fill in the top of the form: your initials, the team number, and the enumeration area code (the same enumeration area code you wrote on the *Registration Form)*. Place cardboard underneath the first set of *Lab Request Forms* (set in duplicate) as they are self-carbonating and pen marks will go through to the next set.

Open the label envelope used for the respective participant, and:

* Only place barcode labels if you will collect blood from the respective participant.
* If collecting blood from the mother, peel off the WHITE labels and place:

i) 1 label on the filter paper, and

ii) 2 labels on the ‘Mother ID Label’ column of the *Lab Request Form.*

* If collecting blood from the infant, peel off the YELLOW labels and place:

i) 1 label on the filter paper, and

ii) 2 labels on the ‘Infant ID Label’ column of the *Lab Request Form.*

* The ‘mother barcode label’ and the ‘infant barcode label’ corresponding to the same mother-infant pair should be placed on the same row. The left side of the form will list all the WHITE ‘mother barcode labels’, and the right side of the form all the YELLOW ‘infant barcode label’.
* If interviewing a caregiver, you will not be collecting a blood specimen from the mother. In this case, write ‘NA’ in the ‘Mother ID Label’ column. If the mother refused to provide a blood sample, do NOT place a ‘mother barcode label’ on the form.
* If interviewing a mother whose infant is deceased, you will not be collecting a blood specimen from the infant. In this case, write ‘NA’ in the ‘Infant ID Label’ column. If the mother refused their child’s blood sample, do NOT place an ‘infant barcode label’ on the form.
* For each mother-infant pair, write on the form the following information: i) the survey date, ii) the number of spots collected, iii) whether the participant indicated that we should send her/her infant’s HIV test result to her local clinic, and iv) whether identifying information was collected for the participant. Make sure that the information mentioned on the *Lab Request Form* is consistent with the *Consent Form*. Once you leave the participant’s house you will be unable to link the consent form with the *Lab Request Form*, so it is very important that you crosscheck the two forms while filling in the *Lab Request Form*.

**How to collect identifying information**

While the survey is anonymous, participants will be asked to provide identifying information (i.e., name, date of birth, national ID number, address) so that they can receive the test results of themselves and their infants; these will be linked with their blood samples using a numerical barcode label. The identifying information (i.e., name, date of birth, national ID number, address) will be collected in a separate dataset on the tablet. This will be demonstrated during the training.

**How to collect the Blood Sample**

Finger prick blood samples will be collected from all living mothers and heel/toe prick blood samples from living infants born 18-24 months prior to the survey date.

Prepare the mother for the blood draw:

* Ensure that the woman is seated comfortably. Explain the procedure and reassure her; be sure to answer all questions truthfully and comprehensively.
* Put the participant at ease by chatting about something neutral.
* Make sure that the filter paper is labeled with two labels.
* Make sure that you have gloves on.

How to take the blood sample:

* Take the participant’s thumb, select the side of the thumb and clean with cotton wool, which have been lightly soaked in alcohol. Use gentle strokes to do this and be sure to remove all traces of grease and dirt.
* Then dry the thumb with cotton wool using firm strokes to stimulate the blood supply to the fingertip.
* Puncture the fingertip using the sterile lancet provided. Be sure that the puncture is deep enough to collect enough blood to fill all the circles on the card.
* Working quickly and holding the filter paper by the edges, collect enough blood to fill all five circles on the blood collection card.
* Apply gentle pressure to the finger and allow a large drop of free-flowing blood to collect at the puncture site.
* Transfer the blood to filter paper by gently touching the filter paper to the drop of blood on the finger.
* Do not smear the blood onto the filter paper.
* Be sure to apply the blood to one side of the card only.
* Discard the used lancet and the cotton wool in the biohazard bag.
* If there is insufficient blood, obtain a second sample from a second finger using the same procedure described above.

You will then proceed to collect a heel/toe prick blood sample from the 18-24 month old infant. Request the mother to sooth and hold her baby so that s/he does not move during the procedure. Warm the heel/toe if possible, swab it with alcohol, allow it to dry, and hold the heel with one hand so that the flesh of the heel is protruding. While firmly holding the heel in one hand, hold the lancet in the other hand and stick it firmly into the bulging heel. The lancet should be pricked perpendicular to the skin of the heel.

After the blood draw:

* After collecting the blood samples, place the filter paper(s) in the drying rack, while making sure they do not touch or overlap, so that the blood samples do not get contaminated. This will allow the filter papers to dry while you continue to administer questionnaires and collect blood samples throughout the day.
* Ask the mother/caregiver if she has any questions about the procedure; answer them.
* Remind the participant that she will be able to pick up her HIV test results at the local clinic within at least 2 months using her national ID.
* Thank them for the blood sample. Reassure them that the pain will go away soon.

**How to conclude the household visit**

Materials:

* Participant incentives
* *Participant Incentives Form*

Thank the mother/ caregiver for her participation in the survey, and give her the incentive [*delineate incentive*]. After receiving the incentives, the participant should sign the *Participant Incentive Form*. Remember to take your time in saying good-bye and not rush this process.

**Chapter 8. LOGISTICS**

Materials:

* Plastic containers for completed dried filter papers
* Level Files for completed forms
* Glassine envelopes

**At the end of each day of fieldwork**, after you return to the place where you are housed, complete the activities described below.

Regarding the filter papers:

* Allow the filter papers to dry for at least three hours. It is likely that this will have to take place overnight and that the drying racks will be stored in the trunks overnight.
* After the filter papers have dried for at least three hours, place each filter paper back into a glassine envelope. This may happen the following morning.
* Make sure that the silica gel is still in each plastic bag and that it has not turned pink. If so, replace the silica gel packet with another one.
* Put all the individual plastic bags with completed filter papers into a plastic container, labeled “completed filter papers”.

Regarding the forms used during data collection:

* All the forms you filled in during the day should be placed in the corresponding binder (for example, the *Completed Registration Forms binder*).
* If your team has not fully covered the enumeration area you are in and hence the following day you will be collecting data in the same EA, prepare your forms for the next day and make any necessary notes. For example, remember that as long as you are in the same EA the new *Registration Form* is simply a continuation of the previous form.

Regarding tablets:

* Back-up the tablets at least once per day and ensure they are charging overnight.
* Remember, you will be in the field all day, so if your tablet is not charged every night it is likely to run out of battery during the day, making it impossible for you to administer questionnaires and disrupting the overall data collection schedule.
* Tell your team leader and document on your notebook if you had any problems with the tablet you used that day. At the end of the survey round when you come back to the office, tell the appropriate staff about the problems you encountered. Depending on the problem, the tablet might need to be replaced and/or repaired.

**At the end of each survey round**, you will submit all the forms and filter papers to the office. In preparation for this ‘check in’ process, you will need to summarize the forms and data collected using the *Data Return Form*. This form should be prepared for each enumeration area covered in the survey.

* Start by filling in some of the fields from the top part of the form: team number, data capturer (who will be submitting the data to the office), enumeration area, district, and province. The date and name of data staff will be filled in at the office, during data check in.
* Based on the *Selected Mothers and Infants List*, count the total number of 18-24 month mother-infant pairs selected for screening.
* Based on the *Screening Forms*, count the total number of households visited, number of 18-24 month mother-infant pairs visited, number of eligible 18-24 month mother-infant pairs, number of ineligible 18-24 month mother-infant pairs, and number of ‘other’ mother-infant pairs/mothers (e.g., abandoned, no one at home, refusal to being screened).
* Based on the *Deceased Infant and Deceased Mother Forms*, count the total number of such mother-infant pairs and mothers in the EA.
* Based on the *Ineligible Mothers Forms*, count the total number of 18-24 month mother-infant pairs in which the mother was 14 years old or under and hence ineligible to participate.
* Based on the *Registration Forms*, count for different types of mother-infant pairs (the mother and infant are alive, only the mother is alive, alive infant and his/her caregiver) and the different types of mothers (mother or caregiver)

i) the number of mother-infant pairs and mothers that were eligible and those who were enrolled;

ii) the number of 18-24 month mother-infant pair consent forms for which the mother/ caregiver agreed to the questionnaire, mother DBS, and infant DBS

iii) the number of 18-24 month mother-infant pair questionnaires conducted (if attributed a tablet number), and the number of Mother and Infant *Verbal Autopsy Comments Sheets*.

* Based on the *Lab Request Forms*, count for different types of 18-24 month mother-infant pairs (the mother and infant are alive, only the mother is alive, alive infant and his/her caregiver):

i) the number of mother DBS collected

ii) the number of infant DBS collected

iii) the number of mothers/ caregivers for which identifying information was collected

It is extremely important that the *Data Return Form* is filled in carefully, as this represents a summary of the data collected in each EA. If the form is filled in incorrectly, the person doing the data check in will have to re-count all forms for each catchment area, resulting in additional work and much wasted time for everyone involved.

**OTHER COMMENTS**

* The use of wraps for the women on the team is highly recommended as its use clearly shows respect to the person you are visiting. Men should refrain from wearing hats.
* Also ensure at *each* entry point in the household that you ask permission to enter. This includes entry at the premises, entry into a room, use of a stool or chair, etc. Think about all the ways that you can put the participant in control of the interaction.
* If a mistake is made on any of the forms, cross out the error with an ‘X’ and then circle the correct response.