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

**STANDARD OPERATING PROCEDURES**

**Blood Samples Handling**

The following guidelines outline the handling of the blood samples collected during the survey.

**PART I: Submitting the Blood Samples to the Laboratory**

After each team checks in the office and submits the data they collected, the first priority is to conduct all the necessary activities related to the blood samples, so that they can be submitted to the laboratory as soon as possible after data collection. Please find below a description of the activities.

**For the Data Entry Clerk:**

The data entry clerk should check and enter the *Lab Request Forms* in the Access database:

* Organize the *Lab Request Forms* by team and enumeration area (EA): All the *Lab Request Forms* from a EA should be sequential, and then the *Lab Request Forms* from the EAs conducted by the *same team* should be sequential.
* Examine the *Lab Request Forms*.

How to read the Lab Request Form

The forms have two sections: i) the top of the form (data capturer initials, team no), and ii) the eight-column table.

18-24 month old Mother-Infant pairs:

In most cases, blood samples will have been collected from both the mother and the infant. However, in some cases only the mother blood sample OR only the infant blood sample will have been collected. If blood samples were collected from both mother and infant, the data capturer will have filled in the *Lab Request Form* as follows (in the order of the columns):

* The date of the specimen collection;
* 18-24 month-old M-I pair
* WHITE ‘mother barcode label’ (format EMPxxxxx);
* The number of blood spots on the mother’s filter paper;
* YELLOW ‘infant barcode label’ (format EBPxxxxx); this label should have the same number as the mother’s sample;
* The number of blood spots on the infant’s filter paper;
* For each *Lab Request Form*, check that all the labels on the form have a corresponding filter paper. If there is an inconsistency, let the appropriate staff member know immediately. If the filter paper was collected and it was not registered on the *Lab Request Form*, you will have to make sure it does not ‘belong’ to a different EA. (You can verify the ‘mother barcode labels’ registered in each EA based on the *Registration Forms*.) If the filter paper was not registered on the *Lab Request Form*, print a new label with the same ID to be added to the correct EA. *All filter papers need to be registered on the Lab Request Forms.*
* All the WHITE ‘mother barcode labels’ should be placed on the left side of the *Lab Request Form*, and all the YELLOW ‘infant barcode labels’ on the right side of the form.
* Enter the *Lab Request Forms* in the Access database:
* Enter the Team number. (You will enter all the *Lab Request Form*s for the same EA; that is why it is important to *first* arrange the forms by team number.)
* Start entering information about each mother-infant pair from that EA, starting with the mother. Scan the WHITE ‘mother barcode label’ and enter the ‘No. of spots’ (1 to 5) and the ‘*Send result’* field (choose ‘Yes’ or ‘No’); then, if applicable, scan the YELLOW ‘infant barcode label’ and enter the ‘*Send result’* field (‘Yes’/ ‘No’). For all 18-24 month M-I pairs enter the ‘Personal Info Collected’ field (‘Yes’/’No’).
* If by mistake you scanned non-paired labels (e.g. EMP00002 and EBP00003), you will receive an error message ‘*Please enter valid Mother & Infant’s ID labels’* and will have to correct the information for the respective mother-infant pair.
* If there is no WHITE ‘mother barcode label’ on a specific row, tick the column ‘*Mother’s Blood NOT Collected?’*. This will prompt you to enter ONLY the information about the infant. Similarly, if there is no YELLOW ‘infant barcode label’ on a specific row, after you enter the information about the mother tick the column ‘*Infant’s Blood NOT Collected?’*. Otherwise, you will receive an error message ‘*Please enter valid Mother & Infant’s ID labels’.*
* After you entered all the *Lab Request Forms* from the same EA, press ‘Clinic Summary’. A summary message will be displayed on the screen *‘You entered XX WHITE labels and XX YELLOW labels’*. Check these numbers against the total number of Mother DBS samples and Infant DBS samples entered on the *Data Return Form* for the same clinic code. In the event of an inconsistency, count *all* the WHITE and YELLOW labels placed on the *Lab Request Forms* you just entered (from the same CA). Counting these labels will tell you if you did not enter any mother-infant pairs or mothers from the *Lab Request Forms*; enter any labels you missed. After double-checking the total number of labels on the forms, correct the *Data Return Form* if there is still an inconsistency.
* After you checked the summary of the labels entered in that CA, proceed to enter the *Lab Request Forms* for the next clinic code by pressing *‘Add New Clinic’*.

When you have finished entering all the *Lab Request Forms* from the entire round, they can be submitted to the laboratory.

**For Data Department:**

After the Data Entry Clerk finished entering the *Lab Request Forms* in the Access database, the Assistant Data Manager will make a few final preparations before submitting the blood samples to the laboratory.

* Generate the lists of mother-infant pairs for which we will submit samples to the lab from Access (per batch):
* The list of PAIRED 9-18 month mother-infant pairs
* The list of 9-18 month mother-infant pairs for which the *WHITE mother barcode label is missing*
* The list of 9-18 month mother-infant pairs for which the *YELLOW infant barcode label is missing*

Each of these lists should be prepared *by team* and within each team sorted according to the ID number. These lists are essential to timely and accurate lab processing. Provide the lab with i) a hard copy, and ii) a soft copy of these lists. Hence, in addition to printing these lists, before leaving the office email the documents to the lab (cc: Data Manager, Research Coordinator).

* Before leaving the office, make sure you are bringing two copies of the *Specimen Receipt Form*.
* Pack the *Lab Request Forms* and filter papers *by team number*.
* Submit the blood samples to the lab *in the morning* to allow adequate checking of the filter papers. This is important as it will allow us to know with certainty the number of filter papers submitted to the lab, in the eventuality of any future inconsistencies.
* Fill in two copies of the *Specimen Receipt Form*.
* Leave the filter papers at the lab and the *yellow copy* of the *Lab Request Forms* for their records. Make sure you bring back to the office the *blue copy* of the *Lab Request Forms*.
* Upon returning at the office, ensure that study staff verify and sign the *Specimen Receipt Form*.

**PART II: Providing Participants with Their HIV Results**

The Data Assistant Manager should follow up with the lab whether the blood samples were tested within 14 working days. As soon as confirmation is received from NMRL that the blood samples were tested, request that the HIV test results are sent to [*study institution*] as soon as possible.

We made a commitment to our study participants to provide their HIV test results within 4 weeks 2 months from the survey date. Therefore, once the results of the tests are received at [*study institution*] office, attend to the following activities immediately:

1. *Merge the database* received from the lab (the HIV test results) with the [*study institution*] Lab Requests (developed in Part I)
2. *Examine the merged dataset and take note of any inconsistencies*. The lab is instructed to conduct the following tests depending on the type of mother-infant pairs:

* For the PAIRED 18-24 month mother-infant pairs (where we collected both mother and infant DBS):
* Mother ELISA for all mother DBS samples
* Infant DNA PCR if the Mother ELISA was HIV+
* The list of 18-24 month mother-infant pairs for which the *WHITE mother barcode label is missing*
* Infant DNA PCR for all infant DBS samples
* The list of 18-24 month mother-infant pairs for which the *YELLOW infant barcode label is missing*
* Mother ELISA for all mother DBS samples

Within the batch of DBS samples submitted to the lab, check that you received the results of all the necessary tests. All the checks will be conducted by EA [or by clinic code]. More specifically, you will be prompted to enter the clinic code ‘xxxxx’. If the HIV test results were not provided by the lab or merged with the Lab Request Form data, you will receive the following message: *“No HIV test results data available”*. If the HIV test results were merged with the Lab Request Forms data, you will receive a report indicating whether any HIV test results are missing for that particular catchment area or if the data is complete. More specifically, you will receive a report regarding the following checks:

1. There is a Mother ELISA result for each 18-24 month mother-infant pair where we collected both mother and infant DBS.
2. There is an Infant DNA PCR result for each 18-24 month mother-infant pair where: i) we collected both mother and infant DBS, and ii) the mother DBS was HIV positive.
3. There is an Infant DNA PCR for each 18-24 month mother-infant pair with a missing mother DBS.
4. There is a Mother ELISA for each 18-24 month mother-infant pair with a missing infant DBS.

For each of these checks (2a to 2d) you will receive a list of the study IDs for which the ELISA and/or the DNA PCR test result is missing (as applicable). Notify the lab of any such inconsistencies and address them as soon as possible.

1. *Print the HIV test results to be sent back to local health facilities:*

From the merged database, you will print the HIV test results for all the mother-infant pairs. All the checks will be conducted by catchment area [or clinic code]. More specifically, you will be prompted to enter the clinic code ‘xxxxx’ and a list of messages will be generated.

For each mother-infant pair with a request to send the results to the local facility, a message will be generated based on the mother and/or infant’s HIV test results and whether this information was requested:

1. For the 18-24 month mother-infant pairs where we collected both mother and infant DBS, one of the following messages will be generated as applicable:

*‘Clinic code: yyyy. Name, date of birth, national ID, address. EMPxxxxx: The mother is HIV positive. EBPxxxxx: The infant is HIV positive.’*

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EMPxxxxx: The mother is HIV positive. EBPxxxxx: The infant is HIV negative.’*

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EMPxxxxx: The mother is HIV negative. EBPxxxxx: The infant’s blood was not tested because the baby could not have been exposed to HIV from the mother.’*

1. For the 18-24 month mother-infant pairs with missing mother DBS, one of the following messages will be generated as applicable:

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EBPxxxxx: The infant is HIV positive.’*

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EBPxxxxx: The infant is HIV negative.’*

1. For the 18-24 month mother-infant pairs with missing infant DBS, one of the following messages will be generated as applicable:

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EMPxxxxx: The mother is HIV positive.’*

*‘Clinic code: xxxxx. Name, date of birth, national ID, address. EMPxxxxx: The mother is HIV negative.’*

Print the list generated for each EA [or clinic code]. Cut along the dotted line that separates the messages of different mother-infant pairs printed on the same page.

1. *Print the participant’s name, date of birth, national ID, and address on a label*: Print the clinic code, *the participant’s name, date of birth, national ID, and address* on one label. For each mother-infant pair and mother, place the label on the back of the envelope.
2. Place the paper with the HIV test result in the corresponding envelope. Make sure the envelope matches the *participant’s details* printed on the HIV test result paper.
3. Package the HIV test results corresponding to each health facility separately. The Research coordinator will arrange their delivery to the respective health facility.
4. Develop a list of infants with a newly diagnosed HIV infection per study results and arrange for in-person return of results to the household.

As part of the study protocol, we have committed to in-person expedited return of results for the following participants:

1. Infants with *newly diagnosed* HIV infection. These are infants who meet the following criteria:
   1. Mother/caregiver reported during the questionnaire that the infant has unknown HIV status
   2. Mother/caregiver reported during the questionnaire that the infant’s most recent HIV test (prior to the survey) was negative

Mothers/caregivers who reported that the infants have known HIV infection (i.e., a positive HIV test whether or not they are on ART) are not new HIV diagnoses and thus do not require expedited, in-person result return

1. Mothers who report current HIV infection but are found on HIV confirmatory testing to have no evidence of HIV infection (i.e., are HIV negative)