Summary of Changes Included in the Full Protocol Amendment of:

IMPAACT 2009

Pharmacokinetics, Feasibility, Acceptability, and Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy and Postpartum in Adolescents and Young Women and their Infants

The Amended Protocol is Identified as:

Version 2.0, 14 January 2020

DAIDS Study ID #30020
IND #136,735 held by DAIDS

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Information/Instructions to Study Sites from the Division of AIDS

The information contained in this protocol amendment impacts the IMPAACT 2009 study, including the study informed consent forms (ICFs), and must be submitted to site Institutional Review Boards (IRBs) and/or Ethics Committees (ECs) as soon as possible for their review and approval. Approval must also be obtained from other site regulatory entities if applicable per the policies and procedures of the regulatory entities. All IRB/EC and regulatory entity requirements must be followed. All required approvals for protocol Version 2.0 must be obtained prior to initiation of the PrEP Comparison Component.

Upon receiving IRB/EC approvals and any other applicable regulatory entity approvals, all sites are required to submit an amendment registration packet to the DAIDS Protocol Registration Office (DAIDS PRO) at the Regulatory Support Center. Sites will then receive a registration notification for the amendment after the DAIDS PRO verifies that all required registration documents have been received and are complete. Receipt of this notification will be confirmed as part of the PrEP Comparison Component site-specific study activation process for this study.

Please file this Summary of Changes, Version 2.0 of the protocol, corresponding site-specific ICFs, all associated IRB/EC and regulatory entity correspondence, and all correspondence with the DAIDS PRO in your essential documents files for IMPAACT 2009.
**Summary and Rationale**

Modifications incorporated into the protocol include the following:

- The study eligibility criteria have been modified as follows:
  - The qualifying laboratory values have been corrected. The requirement for the laboratory values to be Grade 1 or normal per the DAIDS Table for Grading of the Severity of Adverse Events (Corrected Version 2.1, dated July 2017) remains while the corresponding laboratory values are corrected for consistency with the grading table.
  - The maternal entry criteria pertaining to estimated creatinine clearance (CrCl) have been updated to remove reference to Grade 1 for consistency with the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events.
  - Literacy in one or more of the study languages has been added as an inclusion criterion for maternal participants in the PrEP Comparison Component to ensure adherence to the protocol requirements for SMS messaging and completion of computer-assisted self-interviewing (CASI) questionnaires.

- The laboratory specimens to be obtained for exploratory objective 2.5.1 have been modified to permit collection of fresh stool for infants, vaginal pH testing has been removed, and an collection of an environmental swab has been added.

- The documentation expectations for the Integrated Next Step Counseling (iNSC) and SMS mHealth package have been clarified. Edits have been made to Section 5 to specify that completion of iNSC counseling sessions and delivery of the mHealth SMS package will be documented in the study database.

- Edits have been made to Sections 5 and 6, the Schedules of Evaluations, and the sample informed consent forms for the PrEP Comparison Component to clarify the frequency of SMS messages post visit.

- Prospective collection of reported social harms has been added to all maternal follow-up visits during the PrEP Comparison Component to capture and facilitate review of these events by the Clinical Management Committee (CMC).

- The Adverse Event (AE) grading and participant management guidelines for maternal creatinine and creatinine clearance (CrCl) have been clarified. The Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, referenced in protocol Section 7.3.3, provides severity grading for creatinine and CrCl based on both absolute value and change from baseline. Given the anticipated physiologic changes that occur during pregnancy and in the postpartum period, change from baseline does not provide a valid measure of renal function over time for maternal participants in IMPAACT 2009, who will enter the study while pregnant and remain in follow-up through 26 weeks postpartum.

- The safety-related data collection requirements for maternal and infant participants in the PrEP Comparison Component have been clarified and expanded to capture and facilitate the review of less severe adverse events (AEs) and laboratory test results by the CMC.

- The blood collection requirements and timing for conducting resistance testing have been clarified, in Sections 6.3.1, 6.3.2, 13.5.5, and Appendices IID and IIE, as applicable.
• Information regarding the data to be maintained in the computer application used to track and send SMS messages has been added to Section 13.8 and to the sample informed consent form in Appendix VII.

• The sample informed consent form in Appendix VII has been updated to clarify the types of questions participants will answer via computer survey.

• In accordance with ICH GCP E6 4.8.10(n) and DAIDS requirements, Section 11.2 and the sample informed consent forms in Appendices VI, VII, VIII, and IX have been updated to state that other U.S., local and international regulatory entities may review study records.

• The sample informed consent forms are updated where applicable to reflect the current requirements of the Common Rule (per United States Code of Federal Regulations 45 CFR 46).

• The protocol team and study site rosters have been updated to reflect current membership. Other administrative updates and corrections have been incorporated throughout the protocol for accuracy, consistency, and clarity. The table of contents has been updated to reflect current protocol sections and page numbers and to include lists of tables and figures.

• Modifications specified in protocol V1.0 Letter of Amendment (LoA) #1, (dated 1 March 2018) and Clarification Memorandum (CM) #1 (dated 2 April 2019) have been included.

• Other modifications, clarifications and administrative edits to improve consistency across protocol sections have been incorporated.

Implementation

Modifications of protocol text are described in the section below, generally listed in order of appearance in the protocol.

1. Throughout the protocol, the version number was updated to FINAL Version 2.0, dated 14 January 2020. A protocol signature page corresponding to Version 2.0 has been added. External web links have been confirmed and corrected, as applicable, throughout the protocol. Additionally, the cover page was updated to include the IND number (#136,735).

2. The protocol team and study site rosters have been updated to reflect current membership.

3. Sections 3.2.2, 6.2.2.1, 6.2.2.2, 6.2.2.3, 6.4.2.2 and Appendix IIC were updated to add fresh stool as a specimen that may be collected for the infant gut microbiome assessment.

4. In inclusion criteria 4.1.1.8, 4.2.1.6, and 4.2.3.3 the laboratory values were corrected for consistency with the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (Corrected Version 2.1, dated July 2017). Additionally, exclusion criterion 4.1.2.4 was revised for consistency with these modifications applied to the study entry criteria.
5. Inclusion criteria 4.1.1.8 and 4.2.1.6 have been modified to remove reference to Grade 1 estimated creatinine clearance (CrCl) for consistency with the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (Corrected Version 2.1, dated July 2017).

6. Inclusion criterion 4.2.1.13 was added.

7. In Section 5.3.2, additional details regarding the documentation expectations for the Integrated Next Step Counseling (iNSC) sessions and delivery of the mHealth SMS package have been added. Sections 6.3.3 and 6.7 have been updated for consistency with the revised Section 5.3.2.

8. In Section 5.3.2 clarification has been added regarding the frequency of SMS messages post visit and to state that procedural details will be included in the study-specific Manual of Procedures.

9. Sections 6.1.1.1 and 6.2.1 have been updated to clarify that screening evaluations may be repeated within the 30-day study screening period.

10. In Sections 6.1.3.1 and 6.1.3.2, the infant creatinine testing requirements listed in the visit procedures tables were corrected for consistency with Appendix IC.

11. Section 6.1.3.2 was updated to clarify the infant physical examinations requirements.

12. Sections 6.2.1.1, 6.2.1.7, 13.5.2 and Appendices IIA and IIB were revised to include urine as a specimen that may be collected for maternal chlamydia and gonorrhea testing during the PrEP Comparison Component.

13. In Sections 6.2.1.1, 6.2.1.2, 6.2.1.3, 6.2.1.5, 6.2.1.7, 6.2.3.2, 6.4.2.1 and Appendices IIA and IIB, reference to collection of a vaginal swab for maternal vaginal pH testing has been removed and environmental swab has been added to the maternal microbiome procedures.

14. In Sections 6.2.1.1, 6.2.1.2, 6.2.1.3, 6.2.1.4, 6.2.1.5, 6.2.1.6, 6.2.3.1, 6.2.3.2, and Appendices IIA and IIB, references to SMS care support post visit have been removed.

15. In Section 6.2.1.1, footnote #2 was revised to clarify DBS sampling requirements for Cohort 2 participants.

16. In Sections 6.2.1.2, 6.2.1.3, 6.2.1.4, 6.2.1.5, 6.2.1.6, 6.2.1.7, 6.2.3.2, 6.4.2.1, and Appendices IIA and IIB, a social harms assessment has been added to the maternal behavioral and counseling visit procedures.

17. Reference to Section 13.6 concerning additional considerations for assessment of social harms for maternal participants in the PrEP Comparison Component is added to applicable visit procedural tables throughout Section 6.

18. In Section 6.2.1.4 footnote #1 was added to clarify the rationale for DBS sampling in Cohort 2.

19. In Sections 6.2.1.7 and 6.4.2.1 the required timeframe for pregnancy testing to occur prior to maternal DXA scans has been clarified.

20. Sections 6.3.1 and 13.5.5 have been corrected to state that HIV drug resistance testing will be performed in real-time after transmission has been confirmed.
21. The blood collection requirements for HIV drug resistance testing have been simplified, in Sections 6.3.1, 6.3.2, and Appendices IID and IIE. The blood volume for infant HIV drug resistance testing has been increased by .5mL.

22. Section 6.7 has been updated to specify requirements for delivery of SMS messages in the event that a maternal participant experiences fetal demise or death of her infant.

23. Section 6.9 was revised to clarify the requirements for complete and targeted maternal physical examinations during the PK Component, and to specify the exam findings that must be entered into eCRFs.

24. Section 6.13 was revised to clarify the requirements for complete and targeted infant physical examinations during the PK and PrEP Comparison Components and to specify the exam findings that must be entered into eCRFs.

25. Section 6.15 has been updated to correct an error in the stated study screening period and to clarify the fetal ultrasound report documentation requirements based on gestational age at study entry.

26. In Section 6.16.1, the list of domains included in the demographic and behavioral questionnaires administered during the PK Component was corrected.

27. Section 7.2 has been updated to indicate that during the PrEP Comparison Component all reported social harms will be documented on eCRFs.

28. In Section 7.2.1 the safety-related data entry requirements for maternal participants in the PrEP Comparison Component have been modified to include less severe adverse events (i.e. all Grade 2 or higher) and laboratory test results (i.e. all Grade 2 or higher hemoglobin, white blood cell count, absolute neutrophil count, and platelet count results). Reference to the “IMPAACT Do Not Report List” has also been removed.

29. In Section 7.2.2 the safety-related data entry requirements for infant participants in the PrEP Comparison Component have been modified to include less severe adverse events (i.e. all Grade 2 or higher clinical signs, symptoms and diagnosis). Reference to the “IMPAACT Do Not Report List” has also been removed.

30. Section 7.3.3 was revised to specify that for maternal participants in the PrEP Comparison Component, grading of creatinine and CrCl should be based on absolute value only, not on percentage change from baseline.

31. Section 9.3.2 has been updated to indicate that social harms will be monitored by the CMC through routine review of safety data reports generated by the SDMC.

32. In Section 10.2, the visit frequency for participants in Cohort 2 has been corrected.

33. Section 11.2 and Appendices VI, VII, VIII, and IX have been updated to state that other U.S., local and international regulatory entities may review study records.

34. Section 13.6 has been revised to specify prospective collection of social-harms related information by site staff at all maternal follow-up visits during the PrEP Comparison Component and provide guidance regarding management of participants who report experiencing a social harm.
35. Section 13.8 and Appendix VII have been updated to include information about data storage for the mHealth component.

36. In Appendix V, the clinical management guidelines for maternal increased creatinine and reduced creatinine clearance have been clarified and expanded upon.

37. Appendix VII, Sample Informed Consent Form for PrEP Comparison Component, has been modified as specified below. Modified protocol text is shown using strikethrough for deletions and **bold** type for additions.

**INTRODUCTION**, section added following second paragraph:

Here is a summary of important information about the study:

- The study is testing a medicine called Truvada®, or PrEP used to prevent HIV among young women who are pregnant and not infected with HIV.
- Truvada® is a pill that contains 2 anti-HIV medicines (ARVs), called emtricitabine and tenofovir. These medicines are often used to treat HIV infection, but they are also safe and effective in reducing the chance of becoming infected with HIV when taken by people who are not infected with HIV.
- PrEP is approved in many countries around the world, but not many studies have involved HIV uninfected women while they are pregnant and just after delivery.
- Women will enter the study when they are pregnant and will be in the study for 26 weeks after their baby is born.
- To be in the study, women can choose to take PrEP or not take PrEP. Those who choose to take PrEP will take one pill consistently at about the same time every day.
- While in the study, women and their babies will have clinic visits including physical examinations, blood draws for laboratory tests and DXA scans. Women will answer questions about themselves, their health, and their health behaviors on a computer and will receive weekly SMS messages.
- There are some possible risks for women and babies in the study. One possible risk for women who choose to take PrEP is that the medicine could cause side effects. Regardless of whether they chose to take or not take PrEP, women may experience stigma from being in a study about HIV because people might think that they have HIV.
- There are some possible benefits for women in the study. One possible benefit is that women could gain knowledge and skills that may help minimize the risk of getting HIV or other STIs in the future.
- Your decision on your participation in the study will have no effect on the medical care you and your baby would normally receive. Your access to services, and the benefits and rights you normally have, will not be affected.

More information is given in this form about the study, its risks and benefits. You should feel that After you understand the study before deciding whether, if you decide that you will participate with your baby. If you decide to participate, we will ask you to sign or make your mark on this form. You will be offered a copy to keep.
ABOUT THE STUDY, item #6 (added):

6. You will receive SMS messages as part of this study

As part of finding out if you qualify for this study, we will confirm that you have access to a mobile phone that is able to receive SMS messages, and confirm that you agree to receive SMS messages. For mothers who decide to take PrEP, we will also ask whether you are able to send SMS messages.

Whether you decide to take PrEP or not, all mothers will receive routine SMS messages, starting the week you enter the study. These messages will give you information about pregnancy and infant care.

Mothers who take PrEP will also receive weekly messages. The weekly message will ask how you are doing; these messages will not ask specifically about HIV or PrEP. You will be asked to respond to each weekly message within 48 hours and if you do not respond you may receive an additional text message or someone from the study team may try to call you. Someone from the study team may also call you if you respond to the message and ask for help.

BEING IN THE STUDY, item #10 (formerly item #9), If you and your baby qualify, you will enter the study, bulleted list under For all mothers, on the day you enter the study, we will:

- Ask about your health and the medicines you take
- Give you a physical exam
- Have you talk with a counselor about your health behaviors
- Have you complete a survey on the computer, where you will answer questions about yourself, your health, and your health behaviors
- Collect your blood (12 mL or about 2.5 teaspoons) for tests. These tests will:
  - Confirm you are HIV-uninfected
  - Check if you have syphilis or herpes
  - Check if any PrEP drug is in your blood
- Save some of the blood in case you become infected with the HIV-virus during the study for extra HIV tests.
- Confirm that you agree to receive SMS messages. You will receive SMS messages after each visit. These messages will give you information on the how to care for your baby while you are pregnant and after your baby is born.
- Collect vaginal swabs or urine to check if you have sexually transmitted infections such as chlamydia or gonorrhea and to check the type of bacteria present that are normally found in the vagina. For these specimens, a small swab is inserted into the vagina to collect some mucus.
- Collect rectal swabs, by inserting a small swab into the rectum to get some of the fluid. If you prefer, the study staff can give you instructions so that you can collect this specimen yourself. You do not have to agree to this collection. We will ask you later if you agree to have a rectal swabs collected. This testing will be done later in the study, so you and your doctor won’t get the results of these tests.
**BEING IN THE STUDY**, item #10 (formerly item #9), *If you and your baby qualify, you will enter the study*, bullet 3 under *For mothers taking PrEP*, we also will:

- Confirm that you agree to receive SMS messages about taking PrEP. You will receive SMS messages after each visit. These messages will give you information on taking PrEP and asking how you are doing. The messages will not ask specifically about HIV. You will be asked to respond to these messages within 48 hours.

**BEING IN THE STUDY**, item #11 (formerly #10), *You will return to the study clinic for visits every 4 weeks while you are pregnant*, bulleted list under *For all mothers*, at these visits we will:

- Review your medical records
- Ask about your health and the medicines you take, **and your relationships**
- Give you a physical exam
- Have you talk with a counselor about your health behaviors
- Have you complete a survey on the computer, where you will answer questions about **yourself, your health, and your health behaviors**
- Collect your blood (up to 14 mL or about 3 teaspoons) for tests. At different visits, the tests will:
  - Check how well your liver and kidneys are working
  - Confirm that you are HIV-uninfected
- Save some of the blood in case you become infected with the HIV-virus during the study for extra HIV tests
- Following your visit, you will receive SMS messages that will give you information on the how to care for your baby while you are pregnant and after your baby is born.

**BEING IN THE STUDY**, item #11 (formerly #10), *You will return to the study clinic for visits every 4 weeks while you are pregnant*, bullet 7 under *For mothers taking PrEP*, we also will:

- Following your visit, you will receive SMS messages that will give you information on taking PrEP and asking how you are doing. These messages will not ask specifically about HIV. You will be asked to respond to these messages within 48 hours.

**BEING IN THE STUDY**, item #12 (formerly #11), *You and your baby will have a visit soon after delivery. Then you will have 3 more visits over 26 weeks*, bulleted list under *When you come to the clinic with your baby for the visit soon after delivery and when your baby is 6, 14, and 26 weeks of age we will*:

- Review your and your baby’s medical records
- Ask about your and your baby’s health and the medicines you take, **and your relationships**
- Ask about how you are feeding your baby
- Give you and your baby a physical exam
- Have you talk with a counselor about your health behaviors
- Have you complete a survey on the computer, where you will answer questions about **yourself, your health, and your health behaviors**, and experience receiving SMS messages throughout the study.
- Collect a vaginal swab or urine at your final visit to check for infections such as chlamydia or gonorrhea (**at the Week 26 Postpartum visit only**)
- Collect two additional vaginal swabs to check the type of bacteria present (**at the Week 6 and Week 26 Postpartum visits only**).
• Collect rectal swabs to check the type of bacteria present (*at the Week 6 and Week 26 Postpartum visits only*)

• Take blood from you (up to 20 mL or 4 teaspoons) for tests that will:
  – Check your cells
  – Check how well your liver and kidneys are working
  – Check if you have Hepatitis B (a disease of the liver) - *at the Week 26 Postpartum visit only*
  – Check if you have syphilis or herpes - *at the Week 26 Postpartum visit only*
  – Confirm you remain HIV uninfected

• Save some of the blood in case you become infected with the HIV-virus during the study for extra HIV tests

• Following your first two visits, you will receive SMS messages that will give you information on the how to care for your baby after your baby is born.

• Take blood from your baby (up to 1.5 mL or about ½ teaspoon) for tests that will:
  – Confirm your baby’s kidneys are working well (at the first and final visit only)

• Collect rectal swabs or stool from your baby to check the type of bacteria present

• You and your baby will also have DXA scans. DXA stands for a kind of x-ray called dual energy x-ray absorptiometry. DXA scans check how hard and strong the bones are. When having the scan, you lie on a table while a machine passes over their body. Babies are held on a table while the machine passes over their body. The machine does not touch the body and the scan does not hurt. The scan may take up to 15 minutes. Scans will be done for you and your baby shortly after delivery and 26 weeks after birth or delivery. For safety reasons, you must have a pregnancy test before the scan done 26 weeks after delivery to confirm you are not pregnant before having the scan. The results of the scans will not be available while the study is ongoing.

For mothers taking PrEP, we also will:

• Give you supplies of PrEP. At your final visit, we will collect any remaining PrEP from you.

• Provide counseling based on how much PrEP drug is found in your blood. We will use the test results from your past visit to talk to you about how well protected you are from becoming infected with HIV.

• Have you complete a survey on the computer, where you will answer questions about taking PrEP.

• Use blood already collected for tests to confirm how much PrEP drug is in your blood.

• Collect a small amount of fluid from your vagina to check the levels of PrEP drugs in your genital tract.

• Following your first two visits, you will receive SMS messages that will give you information on taking PrEP and asking how you are doing. These messages will not ask specifically about HIV. You will be asked to respond to these messages within 48 hours.

BEING IN THE STUDY, item #13 (formerly #12), *You will have extra visits if you choose to change from not taking PrEP to taking PrEP*, bullet 2 under, *At Visit 1 we will*:

• Ask about your health and the medicines you take, and your relationships

BEING IN THE STUDY, item #13 (formerly #12), *You will have extra visits if you choose to change from not taking PrEP to taking PrEP*, bullet 5 under, *At Visit 1 we will*:

• Have you complete a survey on the computer, where you will answer questions about yourself, your health, and your health behaviors
BEING IN THE STUDY, item #13 (formerly #12), You will have extra visits if you choose to change from not taking PrEP to taking PrEP, bulleted list under, At Visit 2 we will:

- Give you a supply of PrEP
- Teach you about using PrEP and talk to you about your plans for taking your pills
- Ask about your relationships
- Have you complete a survey on the computer, where you will answer questions about yourself, your health, and your health behaviors
- Have you talk with a counselor about your health behaviors
- Collect your blood (4 mL or about 1 teaspoon) for tests. The tests will:
  - Confirm you are HIV-uninfected
  - Check if PrEP drug is in your blood
- Save some of the blood in case you become infected with the HIV-virus during the study for extra HIV tests
- Collect two additional vaginal swabs to check the type of bacteria present
- Collect a rectal swab to check the type of bacteria present
- Following your visit, you will receive SMS messages that will give you information on the how to care for your baby while you are pregnant and after your baby is born

RISKS OF THE STUDY, There is little risk from the study procedures, item #20 (formerly #19), Other Risks:

Also, there may be uncommon or previously unknown risks that might occur. You should report any problems to the study staff immediately. There may also be some social risks to participating in this study. You may feel embarrassed or uncomfortable with some of the questions we will ask you, some of the procedures that will be done, or some of the test results that you will receive. You may also experience stigma as a result of being involved in a study about HIV because people may assume that you have HIV or are HIV-infected. This could mean that you are treated badly in the community or by your family and friends. Being in the study could cause problems with your relationship with your partner if they do not support your choice to participate or use PrEP. Please talk to study staff if this happens. If you have HIV or other infections, knowing this could make you worried. Study staff are trained to help you deal with any feelings or questions you have.

RISKS OF THE STUDY, There could be risks of disclosure of your or your baby’s information, item #22 (formerly #21):

We will make every effort to keep you and your baby’s information private and confidential. Study records and specimens will be kept in secure locations. All specimens and most records will be labeled only with a code number. However, you and your baby’s names will be written on some records that are kept in the clinic. Your name and telephone number will also be stored in the computer system used to send and track SMS messages. Despite our best efforts to keep this information private, it is possible that the information could be obtained by someone who should not have it. If this were to happen, you or your baby could be treated badly or unfairly. You could feel stress or embarrassment. You should contact the study staff at any time if you are worried about your and your baby’s privacy.

Information collected for this study may be used for other research in the future. For example, researchers may use information from this study to try to answer different questions about using PrEP during pregnancy. Any future research done with the information from this study must be approved by the IMPAACT Network. If any future research is done, information
about you or your baby may be used; this information will be labeled with a code number, and
the only link between the code number and your or your baby’s name will be kept here at [site
name]. Your or your baby’s name will not be given to other researchers.

OTHER INFORMATION ABOUT THE STUDY, Study records may be reviewed by study staff and
groups that oversee the study, item #25 (formerly #24), bulleted list:
Groups that oversee the study include:

- [insert name of site IRB/EC]
- [insert name of site drug regulatory authority]
- [insert name of other site regulatory entities]
- The United States National Institutes of Health and its study monitors
- The United States Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP)
- Other U.S., local, and international regulatory entities
- The IMPAACT Network that is coordinating the study
- Gilead Sciences (the company that makes Truvada®)

38. Appendix VIII: Sample Informed Consent Form for Specimen Storage and Future Use

First paragraph:

You have decided to join the study named above with your baby. As part of the study, you will have
blood and urine collected, in addition to vaginal and rectal swabs and vaginal fluid collection. Your
baby will have blood collected in addition to rectal swabs or stool samples. After these samples are
tested for the study, some samples may be left-over. The IMPAACT Network would like to keep
these left-over samples and use them for other research in the future.

Left-over samples could be used for different types of research, item #3, second paragraph, last
sentence (added):

Testing of all your and/or your child’s genes, which is sometimes called whole genome
sequencing, will not be done.

There is little risk to you or your baby, item #4, first paragraph:

When left-over samples are used for research, they are labeled with a code number only. To protect
your and your baby’s privacy, no names are used. However, information such as age, gender, HIV
status, and other health information may be linked to the samples. The only link between the code
number and your and your baby’s name is kept here at [site name]. Your or your baby’s name
will not be given to other researchers.

Information from research using left-over samples may be reviewed by groups that oversee the
research, item #7, bulleted list:

These groups include:

- The IMPAACT Network
- The ethics committees that review and approve the research
- Government and other agencies that pay for the research
• Government and other agencies that monitor the research
• Other U.S., local, and international regulatory entities

39. Appendix IX: Sample In-depth Interview Informed Consent Form

Other information about the qualitative evaluation, item 4, Privacy, third paragraph:

Your records may be reviewed by the sponsor of the study (U.S. National Institutes of Health (NIH), U.S. NIMH) and their representatives, U.S. FDA, The Office for Human Research Protections (OHRP), other U.S., local, and international regulatory entities, [insert name of site] IRB/EC, study staff, study monitors and [insert applicable local regulatory authorities].