APPENDIX VI-A
SAMPLE CONSENT FORM
FOR WOMEN ON ARV MEDICINES WITHOUT TUBERCULOSIS TREATMENT

(Note to Sites: For use with Appendix I-A, I-AMR, and II)

IMPAACT P1026s: Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum, Version, 10.0, dated 2 February 2016
(International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network)

INTRODUCTION

You and your baby are being asked to take part in the research study named above because you are infected with the Human Immunodeficiency Virus (HIV), the virus that causes AIDS, and you are pregnant and are taking one or more of the following HIV medicines during your pregnancy: darunavir/ritonavir twice daily, efavirenz, elvitegravir/cobicistat, darunavir/cobicistat, atazanavir/cobicistat, dolutegravir, tenofovir alafenamide fumarate (TAF)/cobicistat, TAF/ritonavir, TAF alone.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study/allow your baby to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

The correct amount of HIV medicines needed during pregnancy to treat your HIV infection and to protect your baby from HIV infection while being safe for you and your baby is not known for all HIV medicines. In this study, we will compare levels of HIV medicines in pregnant women to levels in non-pregnant adults on the same medicines. If it is found that the your blood levels of HIV medicines are too low, a new dose may be recommended that is not yet approved by the Food and Drug Administration (FDA). We will also see how well the medicines get into vaginal secretions where they may help to keep the amount of HIV in the vagina at a lower level. The amount of medicine found in blood from your baby's umbilical cord will be compared to the amount of medicine in your blood at the time of delivery. We will also look to see how much of the HIV medicine you took is getting into your baby and how safe these medicines are for you and your baby.

This study will be looking at dosing combinations and dose amounts of certain HIV medicines that are not yet approved by the FDA and are still being studied. For example, the higher doses of darunavir twice daily is not approved by the FDA.

WHAT DO I /DOES MY BABY HAVE TO DO IF I AM IN THIS STUDY?

You will continue to obtain and take your HIV medicines as you would normally. No HIV medicines are supplied by this study. Your doctor may ask your permission to report the medicine you take to a national registry, which collects information anonymously on the use of HIV medicine during pregnancy, and any effects these medicines may have on infants. This information is completely confidential and your name will not be used. You do not have to agree to be in the registry.

Your doctor will review with you any dietary recommendations related to the HIV medicines that you are taking. You will need to be on your HIV medicines for at least 2 weeks before your first study visit.

During Pregnancy

- You will need to come to the clinic to make sure you are eligible for the study before you enroll. This may be done as part of your first study visit when you are 20-26 weeks pregnant or 30-38 weeks pregnant, so a separate visit will not be required. We may test you for HIV to confirm your status. At each visit, a history and physical exam, and routine blood tests will be done. Blood will also be drawn to check how well your body is able to fight infection and to check the amount of HIV in your blood. The total amount of blood for these tests is 13 – 16 mL (2½- to 3 ½ teaspoons). At each visit you will be asked about taking your HIV medicines.

- Checking the Amount of HIV Medicine in Your Blood

Sites outside the U.S. should include: Blood that is drawn during this study will be sent to doctors in laboratories in your country or overseas who have special ways of looking at the amount of HIV medicine in the blood.

If you enter the study when you are 20-26 weeks pregnant, repeat blood samples will be taken to measure the amount of HIV medicine in your blood. These blood samples will be repeated when you are 30-38 weeks pregnant. A small plastic catheter (soft tube) will be placed in a vein in your arm during this visit, so that blood can be drawn multiple times, without having to stick you with a needle several times. The tube will stay in place until all of the blood samples are drawn. Depending on the medicine(s) you are taking and the time you usually take them, 7 blood samples over 12 hours, or 8 blood samples over 24 hours will be taken. The total amount of blood taken for these tests will be between 17-19 mL (about 3½ to 4 teaspoons). You will be asked to provide the times of your previous two doses of medicine and to describe the time and amount of your previous two meals. Before these repeat blood samples are taken, the study staff will review with you any dietary recommendations related to the HIV medicines you are taking. Once your HIV medicine levels have been determined, they will be reported back to you and your doctor as soon as possible. If these levels are low compared to those in non-pregnant adults, you and your doctor will be told. You may decide, in consultation with your doctor, to adjust the dose of the medicine(s). The new dose may be higher than the current FDA approved dose. If you and your doctor choose to increase your dose of medicine, you may choose to have repeat blood sampling and drug measurements taken during the pregnancy and after you deliver to assess the levels of medicine in your blood on the new dose.

- Genetic Testing

Some of your blood collected for other tests will be used for genetic testing. Also, if you agree, between birth and 9 days after birth, your baby will have one drop of blood taken for genetic testing of your baby. This test is to see if there are differences in specific genes that may affect the levels of some medicines. Some people break down medicines differently based on their DNA and this can change the levels of the medicines in their bodies. You may decide that you do not want your or your baby's DNA to be tested either now or at another time, by contacting your care provider during the study. You can still participate in this study even if you make this decision. This test will be done later in the study so you will not receive the results of this test. Please read the following statement carefully and then mark your initials in the appropriate space provided:

I agree to allow my DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

I agree to allow my baby's DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

- Checking the Amount of HIV Medicine in Your Vagina

At some of the same times you have blood drawn to check the levels of HIV medicine in your blood, a small amount of vaginal fluid (about 1/8 of a teaspoon) will be taken before you take your dose of HIV medicine and again one, two, and four hours after your dose to check the amount of medicine in the vagina. The samples can be taken by you or your health care provider. Your provider will talk with you about the different ways vaginal fluid can be collected so that it is as comfortable as possible for you. These drug levels and testing will be done in batches later in the study, so you and your doctor won't get results of these tests. If you have a pregnancy condition such as placenta previa (placenta that is implanted in the lower uterus) or broken water bag that would make it unsafe to collect vaginal specimens, they will not be collected.

- Additional study tests if you are taking darunavir/ritonavir twice daily

If you are taking darunavir/ritonavir twice daily, you will be followed more closely during pregnancy and after delivery because these higher dosing combinations are not yet approved by the FDA. You will have an electrocardiogram (a quick test that looks at how your heart is beating) when you enter the study and again after 30 weeks into your pregnancy. If you have not had a test to check for gestational diabetes done as standard of care by your primary care physician, between 24 weeks gestation and delivery, some blood will be taken after a sweet drink to check the level of glucose (blood sugar) in your blood. If the tests are abnormal, you will be followed by your primary care physician. From the time you enter the study until 30 weeks into your pregnancy, you will have a medical history, physical examination, and routine blood tests done every four weeks. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests. From 30 weeks until delivery, a medical history and physical examination will be done every two weeks and routine blood tests will be done every 4 weeks. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests. Two to three weeks after delivery, you will have a medical history, physical examination, and routine blood tests done. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests.

During Delivery

At the time of delivery, a history and physical exam and routine blood tests will be done. Blood will also be drawn to check how well your body is able to fight infection and to check the amount of HIV in your blood. About 18 mL (about 3½ teaspoons) of blood will be drawn. You will be given the results of these tests. After your baby is born, a small amount of blood will also be drawn from the umbilical cord that is attached to the placenta after the placenta has been separated from the baby. This blood comes from the placenta not your baby.

After Delivery

If you are taking efavirenz, elvitegravir/cobicistat, darunavir/cobicistat, atazanavir/cobicistat, dolutegravir, or tenofovir alafenamide fumarate (TAF)/cobicistat, TAF/ritonavir, TAF alone, you will be seen in the clinic 6-12 weeks after you deliver your baby. At this visit after delivery, you will have a history and physical exam, and routine blood tests. Blood will also be drawn to check how well your body is able to fight infection and to check the amount of HIV in your blood. You will be given the results of these tests. Repeat blood samples will be taken to check the amount of HIV medicine in your blood. The total amount of blood to be drawn at this visit is between 30-32 mL (6 to 6½ teaspoons). A vaginal fluid

sample and a vaginal swab will be taken. The vaginal sample can either be collected by you or your doctor. This testing will be done in batches later in the study, so you and your doctor won't get the results of these tests.

If you are taking darunavir/ritonavir twice daily you will be seen in the clinic at 2-3 weeks after you deliver your baby. At this visit after delivery, you will have a history and physical exam, and routine blood tests. Blood will also be drawn to check how well your body is body is able to fight infection and to check the amount of HIV in your blood. Repeat blood samples will be taken to check the amount of HIV medicine in your blood like what was done during your pregnancy. The total amount of blood to be drawn at this visit is between 30-32 mL (6 to 6½ teaspoons). At each visit you will be asked about taking your HIV medicines.

Study Visits for Your Baby

After your baby is born, your baby will be examined 3 times during the study: from birth to 3 days after birth, 5-9 days after birth, and again at 4-6 months of age. During these visits, your baby will be weighed and measured and information about your baby's health will be recorded from his/her medical records. Your baby, if able, will have blood samples taken to determine how much of the antiretroviral medication you took during pregnancy got into your baby and how long it takes to go away. Your baby will have blood samples taken at three time points between birth and 3 days after birth and a fourth sample taken between 5 and 9 days after birth. About 1 mL, or less than ¼ teaspoon *(sites-add locally relevant description of blood volume)* of blood will be taken for each sample. The total amount of blood taken for these tests will be around 3 – 4 mL, about 1 teaspoon *(sites-add locally relevant description of blood volume).*

Each of your baby's study visits will last about *[sites add local information about time for study visits]*.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study will enroll 25 women per drug/drug combination and their babies.

HOW LONG WILL YOU/YOUR BABY BE IN THIS STUDY?

You and your baby will be in this study until 24 weeks after you deliver your baby.

WHY WOULD THE DOCTOR TAKE ME/MY BABY OFF THIS STUDY EARLY?

The study doctor may need to take you and your baby off the study early without your permission if:

- The study is cancelled by the IMPAACT network, U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office for Human Research Protections (OHRP), other local or national regulatory agencies, or the site's Institutional Review Board (IRB) or Ethics Committee (EC). An IRB and EC are committees that watches over the safety and rights of research subjects.
- You are/your baby is not able to attend the study visits as required by the study.
- You need a treatment that you may not take while on study.
- You are not able to take the HIV medicine(s) required by the study.

If you must stop taking the study drug(s) before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

WHAT ARE THE RISKS OF THE STUDY?

The medicines used in this study may have side effects. Your doctor will explain the possible side effects of the medicines you are taking.

Any time a medicine dose is used (both approved and not approved by the FDA), unexpected side effects may occur. If you have any questions concerning the possible side effects of the medicines that you are taking, please ask the medical staff at your site to review them with you.

Risks of Drawing Blood

Blood drawing may cause fainting or lightheadedness or some discomfort. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of a minor infection at the blood draw site. Blood drawing from your baby can also be done by heel stick. Heel stick may cause some discomfort, bleeding or bruising at the site of the heel stick. There is a small risk of infection at the site of the heel stick.

Risks of Collecting Vaginal Fluid and Vaginal Swabs

You may feel slight discomfort when collecting vaginal fluid. This should be minimal.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. You may benefit from having the levels of HIV medicine(s) in your blood measured and having your blood checked for safety effects. If these levels are low compared to those in non-pregnant adults, you and your clinician may decide to increase the dose of the medicine(s). Information learned from this study may help others who have HIV.

WHAT ABOUT CONFIDENTIALITY?

For US Sites
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you/your baby, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you/your baby, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration (FDA).

People who may review your/your baby's records include: the U.S. Food and Drug Administration (FDA), (insert Name of Site) IRB, National Institutes of Health (NIH), the Office for Human Research Protection, study staff, and study monitors. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you/your baby or your/your baby's participation in this research. If an insurer, employer, or other person obtains your written consent to receive research

information, then the researchers may not use the Certificate of Confidentiality to withhold that information.

For sites outside the U.S
Efforts will be made to keep your/your baby's personal information confidential. We cannot guarantee absolute confidentiality. Your/your baby's personal information may be disclosed if required by law. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

Your/your baby's records may be reviewed by the Ministry of Public Health in your country, the FDA, the Office of Human Research Protections (OHRP), the NIH, (*insert name of site)* IRB, Ethics Committee (EC), study staff, and study monitors.

WHAT ARE THE COSTS TO ME?

There is no cost for the study-related clinic visits, examinations, and laboratory tests in this study. Any medical costs for your treatment outside this study, including your prescribed medicines for HIV, will be charged to you or your health insurance company. This study will not cover any cost related to your pregnancy and delivery or care of your baby. You will not receive payment for your participation in this study.

WHAT HAPPENS IF I AM/MY BABY IS INJURED?

If you are/your baby is injured as a result of being in this study, you/your baby will be given immediate treatment for your/your baby's injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health (NIH). You will not be giving up any of your legal rights by signing this consent form.

WHAT ARE MY/MY BABY'S RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part/allow your baby to take part in this study or leave this study at any time. Your decision will not have any impact on your/your baby's participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are/your baby is otherwise entitled.

We will tell you about new information from this or other studies that may affect your/your baby's health, welfare or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:
- name of the investigator or other study staff
- telephone number of above

For questions about your/your baby's rights as a research subject, contact:
- name or title of person on the Institutional Review Board (IRB) or other organization appropriate for the site
- telephone number of above

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in/allow your baby to take part in this study, please sign your name below.

_____ Participant's Name (print)	_____ Participant's Signature and Date
_____ Participant's Legal Guardian (print) (As appropriate)	_____ Legal Guardian's Signature and Date
_____ Study Staff Conducting	_____ Study Staff Signature and Date
_____ Witness' Name (print)	_____ Witness's Signature and Date

APPENDIX VI-B
SAMPLE CONSENT FORM
FOR WOMEN ON ARV MEDICINES WITH TUBERCULOSIS TREATMENT (FIRST LINE AND SECOND LINE)

(Note to Sites: For use with Appendix I-B, I-AMR, and II)

IMPAACT P1026s: Pharmacokinetic Properties of Antiretroviral and Related Drugs during Pregnancy and Postpartum, Version, 10.0, dated 2 February 2016
(International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network)

INTRODUCTION

You and your baby are being asked to take part in the research study named above because you are infected with the Human Immunodeficiency Virus (HIV), the virus that causes AIDS and you are pregnant and are taking HIV medicines and tuberculosis medications as described in one of the tables below.

One of the following HIV medications:	**At least one of the following additional TB medications:**
Efavirenz Lopinavir/ritonavir	rifampicin ethambutol isoniazid pyrazinamide

Or

HIV medications:	**Two of the following TB medications:**
Any	kanamycin amikacin capreomycin moxifloxacin levofloxacin ofloxacin ethionamide/prothionamide terizidone/cycloserine para-aminosalicylic acid (PAS) isoniazid bedaquiline clofazamine delamanid linezolid pretomanid

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study/allow your baby to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

The correct amount of tuberculosis medicines needed during pregnancy to treat tuberculosis infection is not known. When tuberculosis medicines are taken together with HIV medicines TB medicines may decrease the amount of the HIV medicines in the blood, so that the correct doses of the these HIV medicines to protect your baby from HIV infection while being safe for you and your baby is not known. In this study, we will measure levels of tuberculosis medicines and these HIV medicines in HIV-infected pregnant women. We will compare the levels of tuberculosis medicines to those in HIV-uninfected pregnant women on the same tuberculosis medicines. We will also compare the levels of HIV medicines to those in non-pregnant adults without tuberculosis on the same HIV medicines. If it is found that the your blood levels of the HIV medicines are too low, a new dose may be recommended that is not yet approved by the Food and Drug Administration (FDA). The amount of medicine found in blood from your baby's umbilical cord will be compared to the amount of medicine in your blood at the time of delivery**.** We will also look to see how much of the HIV medicines you took are getting into your baby and how safe these medicines are for you and your baby.

This study will be looking at dosing combinations and dose amounts of certain HIV medicines that are not yet approved by the FDA and are still being studied. For example, the higher doses of lopinavir/ritonavir and efavirenz being studied are not approved by the FDA.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

You will continue to obtain and take your HIV and tuberculosis medicines as you would normally. No HIV or tuberculosis medicines are supplied by this study. Your doctor may ask your permission to report the medicine you take to a national registry, which collects information anonymously on the use of HIV medicine during pregnancy, and any effects these medicines may have on infants. This information is completely confidential and your name will not be used. You do not have to agree to be in the registry.

Your doctor will review with you any dietary recommendations related to the HIV and tuberculosis medicines that you taking. You will need to be on your HIV and tuberculosis medicines for at least 2 weeks before your first study visit.

During Pregnancy

- You will need to come to the clinic to make sure you are eligible for the study before you enroll. This may be done as part of your first study visit when you are 20-26 weeks pregnant or 30-38 weeks pregnant, so a separate visit will not be required. We may test you for HIV to confirm your status. At each of these visits you will have a history and physical exam, and routine blood tests. Blood will also be drawn to check how well your body is able to fight infection and to check the amount of HIV in your blood. The total amount of blood for these tests is 13 - 22 mL (slightly more than 4 teaspoons). At each visit you will be asked about taking your HIV medicines.

- Checking the Amount of HIV and Tuberculosis Medicines in Your Blood

  If you enter the study when you are 20-26 weeks pregnant, repeat blood samples will be taken to measure the amount of HIV and tuberculosis medicines in your blood. These blood samples will be repeated when you are 30-38 weeks pregnant. A small plastic catheter (soft tube) will be placed in a vein in your arm for an extended period of time, so that blood can be drawn multiple times, without having to stick you with a needle several times. The tube will stay in place until all of the blood samples are drawn. Depending on the medicine(s) you are taking and the time you usually take them, 7 blood samples over 12 hours, or 8 blood samples over 24 hours will be taken. The total amount of blood taken for these tests will be between 31-35 mL (about 7 teaspoons). You will be asked to

provide the times of your previous two doses of medicine and to describe the time and amount of your previous two meals. Before these repeat blood samples are taken, the study staff will review with you any dietary recommendations related to the HIV medicines you are taking. Your HIV medicine level will be reported back to you and your doctor as soon as possible. If the level is low compared to those in non-pregnant adults, you and your doctor will be told. You may decide, in consultation with your doctor, to adjust the dose of the medicine(s). The new dose may be higher than the current FDA approved dose. If you and your doctor choose to increase your dose of medicine, you may choose to have repeat blood sampling and drug measurements taken during the pregnancy and after you deliver to assess the levels of medicine in your blood on the new dose. The tuberculosis drug levels and testing will be done in batches later in the study, so you and your doctor won't get results of these tests.

- Genetic Testing

Some of your blood collected for other tests will be used for genetic testing. Also, if you agree, between birth and 9 days after birth, your baby will have one drop of blood taken for genetic testing of your baby. This test is to see if there are differences in specific genes that may affect the levels of some medicines. Some people break down medicines differently based on their DNA and this can change the levels of the medicines in their bodies. You may decide that you do not want your or your baby's DNA to be tested either now or at another time, by contacting your care provider during the study. You can still participate in this study even if you make this decision. This test will be done later in the study so you will not receive the results of this test. Please read the following statement carefully and then mark your initials in the appropriate space provided:

I agree to allow my DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

I agree to allow my baby's DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

- Additional study tests if you are taking lopinavir/ritonavir

If you are taking an increased dose of lopinavir/ritonavir, you will be followed more closely during pregnancy and after delivery because this higher dosing combination is not yet approved by the FDA. You will have an electrocardiogram (a quick test that looks at how your heart is beating) when you enter the study and again after 30 weeks into your pregnancy. If you have not had a test to check for gestational diabetes done as standard of care by your primary care physician, between 24 weeks gestation and delivery, some blood will be taken after a sweet drink to check the level of glucose (blood sugar) in your blood. If the tests are abnormal, you will be followed by your primary care physician. From the time you enter the study until 30 weeks into your pregnancy, you will have a medical history, physical examination, and routine blood tests done every four weeks. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests. From 30 weeks until delivery, a medical history and physical examination will be done every two weeks and routine blood tests will be done every 4 weeks. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests. Two to three weeks after delivery, you will have a medical history, physical examination, and routine blood tests done. About 6 mL (slightly more than one teaspoon) of blood will be taken for these tests.

During Delivery

At the time of delivery, a history and physical exam and routine blood tests will be done. Blood will also be drawn to check how well your body is body is able to fight infection and to check the amount of HIV in your blood. You will be given the results of these tests. About 18 mL (about 3½ teaspoons) of blood will be drawn. After your baby is born, a small amount of blood will also be drawn from the umbilical cord that is attached to the placenta after the placenta has been separated from the baby. This blood comes from the placenta not your baby.

After Delivery

You will be seen in the clinic 2-8 weeks after you deliver your baby. At this visit after delivery, you will have a history and physical exam, and routine blood tests. Blood will also be drawn to check how well your body is body is able to fight infection and to check the amount of HIV in your blood. You will be given the results of these tests. If you received injectable TB drugs you will have a hearing test. This hearing test can be scheduled on any day after you deliver. If you are still taking tuberculosis medicines, repeat blood samples will be taken to check the amount of HIV medicine and tuberculosis medicine in your blood. The total amount of blood to be drawn for these tests is between 13-54 mL (about 3 to 11 teaspoons) depending on the tests that will be done. At each visit you will be asked about taking your HIV medicines.

Study Visits for Your Baby:

After your baby is born, your baby will be examined 3 times during the study: from birth to 3 days after birth, 5-9 days after birth, and again at 4-6 months of age. During these visits, your baby will be weighed and measured and information about your baby's health will be recorded from his/her medical records. If you received injectable TB drugs your baby will have a hearing test. This hearing test can be scheduled on any day. Your baby, if able, will have blood samples taken to determine how much of the antiretroviral medication you took during pregnancy got into your baby and how long it takes to go away. Your baby will have blood samples taken at three time points between birth and 3 days after birth and a fourth sample taken between 5 and 9 days after birth. About 1 mL, or less than ¼ teaspoon *(sites-add locally relevant description of blood volume)* of blood will be taken for each sample. The total amount of blood taken for these tests will be around 3 – 4 mL, about 1 teaspoon *(sites-add locally relevant description of blood volume).*

Each of your baby's study visits will last about *[sites add local information about time for study visits].*

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study will enroll 25 women per HIV medicine/tuberculosis medicine combination and their babies.

HOW LONG WILL I/MY BABY BE IN THIS STUDY?

You and your baby will be in this study until 24 weeks after you deliver your baby.

WHY WOULD THE DOCTOR TAKE ME/MY BABY OFF THIS STUDY EARLY?

The study doctor may need to take you and your baby off the study early without your permission if:

- The study is cancelled by the IMPAACT network, U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office for Human Research Protections (OHRP), other local

or national regulatory agencies, or the site's Institutional Review Board (IRB) or Ethics Committee. An IRB is a committee that watches over the safety and rights of research subjects.
- You are/your baby is not able to attend the study visits as required by the study.
- You need a treatment that you may not take while on study.
- You are not able to take the HIV or TB medicine(s) required by the study.

If you must stop taking the study drug(s) before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

WHAT ARE THE RISKS OF THE STUDY?

The medicines used in this study may have side effects. Your doctor will explain the possible side effects of the medicines you are taking.

Any time a medicine dose is used (both approved and not approved by the FDA), unexpected side effects may occur. If you have any questions concerning the possible side effects of the medicines that you are taking, please ask the medical staff at your site to review them with you.

Risks of Drawing Blood

Blood drawing may cause fainting or lightheadedness or some discomfort. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of a minor infection at the blood draw site. Blood drawing from your baby can also be done by heel stick. Heel stick may cause some discomfort, bleeding or bruising at the site of the heel stick. There is a small risk of infection at the site of the heel stick.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you take part in this study, there may be a direct benefit to you, but no guarantee can be made. You may benefit from having the levels of HIV and TB medicine in your blood measured and having your blood checked for safety effects. If these levels are low compared to those in non-pregnant adults, you and your clinician may decide to increase the dose of the medicine(s). Information learned from this study may help others who have HIV and TB.

WHAT ABOUT CONFIDENTIALITY?

U.S. sites:
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you/your baby, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you/your baby, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration (FDA).

People who may review your/your baby's records include the U.S. Food and Drug Administration, the site IRB or Ethics Committee, other national regulatory agencies, the National Institutes of Health, the

Office for Human Research Protections, study staff, and study monitors. Any publication of this study will not use your/your baby's name or identify you/your baby personally
You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you/your baby or your/your baby's participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate of Confidentiality to withhold that information.

For sites outside the U.S.
Efforts will be made to keep your/your baby's personal information confidential. We cannot guarantee absolute confidentiality. Your/your baby's personal information may be disclosed if required by law. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

Your/your baby's records may be reviewed by the Ministry of Public Health in your country, the FDA, the Office of Human Research Protections (OHRP), the NIH, (*insert name of site)* IRB, Ethics Committee (EC), study staff, and study monitors.

WHAT ARE THE COSTS TO ME?
There is no cost for the study-related clinic visits, examinations, and laboratory tests in this study. Any medical costs for your/your baby's treatment outside this study, including your prescribed medicines for HIV and tuberculosis will be charged to you or your health insurance company. This study will not cover any cost related to your pregnancy and delivery or care of your baby. You will not receive payment for your participation in this study.

WHAT HAPPENS IF I AM INJURED?

If you are/your baby is injured as a result of being in this study, you/your baby will be given immediate treatment for your/your baby's injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health (NIH). You will not be giving up any of your/your baby's legal rights by signing this consent form.

WHAT ARE MY/MY BABY'S RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part in this study/allow your baby to take part in this study or leave this study at any time. Your decision will not have any impact on your/your baby's participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are/your baby is otherwise entitled.

We will tell you about new information from this or other studies that may affect your/your baby's health, welfare or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:
- name of the investigator or other study staff
- telephone number of above

For questions about your/your baby's rights as a research subject, contact:

- name or title of person on the Institutional Review Board (IRB) or other organization appropriate for the site
- telephone number of above

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Participant's Legal Guardian (print) (As appropriate)	Legal Guardian's Signature and Date
_____	_____
Study Staff Conducting	Study Staff Signature and Date
_____	_____
Witness' Name (print)	Witness's Signature and Date

APPENDIX VI-C
SAMPLE CONSENT FORM
FOR HIV-UNINFECTED PREGNANT WOMEN ON NO ARV MEDICINES WITH TUBERCULOSIS TREATMENT

(Note to Sites: For use with Appendix I-C and II)

IMPAACT P1026s: Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum, Version, 10.0, dated 2 February 2016
(International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network)

INTRODUCTION

You and your baby are being asked to take part in the research study named above because you are pregnant and are taking tuberculosis medicines during your pregnancy as described in one of the tables below.

At least one of the following TB medications:
rifampicin
ethambutol
isoniazid
pyrazinamide

or

Two of the following TB medications:
- kanamycin
- amikacin
- capreomycin
- moxifloxacin
- levofloxacin
- ofloxacin
- ethionamide/prothionamide
- terizidone/cycloserine
- para-aminosalicylic acid (PAS)
- isoniazid
- bedaquiline
- clofazamine
- delamanid
- linezolid
- pretomanid

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study/allow your baby to take part in this study you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

The correct amount of tuberculosis medicines needed during pregnancy to treat tuberculosis infection is not known. In this study, we will measure the levels of tuberculosis medicines in the blood of women before and after delivery. We will also look to see how safe these medicines are. .

WHAT DO I/MY BABY HAVE TO DO IF I AM IN THIS STUDY?

You will continue to obtain and take your tuberculosis medicines as you would normally. No tuberculosis medicines are supplied by this study. Your doctor will review with you any dietary recommendations related to the tuberculosis medicines that you are taking. You will need to be on your tuberculosis medicines for at least 2 weeks before your first study visit.

During Pregnancy

You will need to come to the clinic to make sure you are eligible for the study before you enroll. This may be done as part of your first study visit when you are 20-26 weeks pregnant or 30-38 weeks pregnant, so a separate visit will not be required. At each of these visits you will have a history and physical exam, and routine blood tests. You will be given the results of these tests. About 6 - 12 mL (slightly more than 2 teaspoon) of blood will be drawn at each visit depending on what TB drugs you are taking.

- Checking the Amount of Tuberculosis Medicine in Your Blood

At 20-26 weeks and 30-38 weeks of your pregnancy, blood samples will be taken to measure the amount of tuberculosis medicine in your blood. A small plastic catheter (soft tube) will be placed in a vein in your arm and will stay there for about a half a day, so that blood can be drawn about 7 times, without having to stick you with a needle more than about once. . The tube will stay in place until all of the blood samples are drawn. Seven (7) blood samples will be taken over 12 hours. The total amount of blood taken for these tests will be about 17 mL (about 3 ½ teaspoons) depending on the number of tuberculosis medicines you are taking. You will be asked for the times and amounts of your previous two doses of medicine and last two meals. The study staff will review with you the best diet for the tuberculosis medicines you are taking. The tuberculosis drug levels will be done in batches later in the study, so you and your doctor won't get results of these tests until about the end of the study.

During Delivery

At the time of your delivery, a history and physical exam and routine blood tests will be done. About 6 mL (slightly more than one teaspoon) of blood will be taken. You will be given the results of these tests.

After Delivery

You will be seen in the clinic 2-8 weeks after you deliver your baby. At this visit you will have a history and physical exam, and routine blood tests. If you received injectable TB drugs you will have a hearing test. This hearing test can be scheduled for any time after you deliver. If you are still taking tuberculosis medicines, repeat blood samples will be taken to determine the amount of TB medicine in your blood. The total amount of blood to be drawn for these tests is between 6 and 29 mL (about 1 to 6 teaspoons) depending on the tests to be done.

Study Visits for Your Baby

After your baby is born, your baby, will be examined 2 times during the study: from birth to 3 days after birth and again at 4 – 6 months of age. During these visits, your baby will be weighed and measured and

information about your baby's health will be recorded from his/her medical records. If you received injectable TB drugs your baby will have a hearing test. This hearing test can be scheduled on any day.

Each of your baby's study visits will last about [sites add local information about time for study visits].

Genetic Testing

Some of your blood collected for other tests will be used for genetic testing to help understand how your body handles your medications based on your genes and DNA. Also, if you agree, between birth and 3 days of age, your baby will have one drop of blood taken for genetic testing of your baby. You may decide that you do not want your or your baby's genes to be tested. Tell your health care provider if you decide this. You can still participate in this study even if you make this decision. This test will be done later in the study so you will not receive the results of this test. Please read the following statement carefully and then mark your initials in the appropriate space provided:

I agree to allow my DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

I agree to allow my baby's DNA to be tested.

Yes_____ No_____ Initials _____ Date _____

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study will enroll 25 women for each tuberculosis treatment and their babies.

HOW LONG WILL I/MY BABY BE IN THIS STUDY?

You and your baby will be in this study until 24 weeks after you deliver your baby.

WHY WOULD THE DOCTOR TAKE ME/MY BABY OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:

- The study is cancelled by the IMPAACT network, U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office for Human Research Protections (OHRP), other local or national regulatory agencies, or the site's Institutional Review Board (IRB) or Ethics Committee. An IRB is a committee that watches over the safety and rights of research subjects.
- You are/your baby is not able to attend the study visits as required by the study.
- You need a treatment that you may not take while on study.
- You are not able to take the tuberculosis medicine(s) required by the study.

If you must stop taking the study drug(s) before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

WHAT ARE THE RISKS OF THE STUDY?

The medicines used in this study may have side effects. Your doctor will explain the possible side effects of the medicines you are taking. If you have any questions concerning the possible side effects of the medicines that you are taking, please ask the medical staff at your site to review them with you.

Risks of Drawing Blood

Blood drawing may cause fainting or lightheadedness or some discomfort. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of an infection at the blood draw site. Blood drawing from your baby can also be done by heel stick. Heel stick may cause some discomfort, bleeding or bruising at the site of the heel stick. There is a small risk of infection at the site of the heel stick.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you take part in this study, there may be no direct benefit to you but you will have more doctor visits where you can be checked that your medicines are safe. Information learned from this study may help others who are pregnant and have tuberculosis.

WHAT ABOUT CONFIDENTIALITY?

For US Sites:
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you or your baby, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration (FDA).

People who may review your/your baby's records include: the U.S. Food and Drug Administration (FDA), (insert Name of Site) IRB, National Institutes of Health (NIH), the Office for Human Research Protection, study staff, and study monitors. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you/your baby or your/your baby's participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate of Confidentiality to withhold that information.

(For sites outside the U.S.)
Efforts will be made to keep your/your baby's personal information confidential. We cannot guarantee absolute confidentiality. Your/your baby's personal information may be disclosed if required by law. Any publication of this study will not use your/your baby's name or identify you/your baby personally.

Your/your baby's records may be reviewed by the Ministry of Public Health in your country, the FDA, the Office of Human Research Protections (OHRP), the NIH, (*insert name of site)* IRB, Ethics Committee (EC), study staff, and study monitors.

WHAT ARE THE COSTS TO ME?

There is no cost for the study-related clinic visits, examinations, and laboratory tests in this study. Any medical costs for your/your baby's treatment outside this study, including your prescribed medicines for tuberculosis, will be charged to you or your health insurance company. This study will not cover any cost related to your pregnancy and delivery or care of your baby. You will not receive payment for your participation in this study.

WHAT HAPPENS IF I AM/MY BABY IS INJURED?

If you are/your baby is injured as a result of being in this study, you/your baby will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health (NIH). You will not be giving up any of your/your baby's legal rights by signing this consent form.

WHAT ARE MY/MY BABY'S RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part/allow your baby to take part in this study or leave this study at any time. Your decision will not have any impact on your/your baby's participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you/your baby are otherwise entitled.

We will tell you about new information from this or other studies that may affect your/your baby's health, welfare or willingness to stay in this study. If you want the results of the study, let the study staff know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:

- name of the investigator or other study staff
- telephone number of above

For questions about your/your baby's rights as a research subject, contact:

- name or title of person on the Institutional Review Board (IRB) or other organization appropriate for the site
- telephone number of above

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part/allow your baby to take part in this study, please sign your name below.

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Participant's Legal Guardian (print) (As appropriate)	Legal Guardian's Signature and Date
_____	_____
Study Staff Conducting	Study Staff Signature and Date
_____	_____
Witness' Name (print)	Witness's Signature and Date

APPENDIX VI-D
SAMPLE CONSENT FORM
FOR POSTPARTUM WOMEN ON ANTIRETROVIRAL MEDICINES AND HORMONAL CONTRACEPTIVES

(Note to Sites: For use with Appendix I-D)

IMPAACT P1026s: Pharmacokinetic Properties of Antiretroviral and Related Drugs During Pregnancy and Postpartum, Version, 10.0, dated 2 February 2016
(International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Network)

INTRODUCTION

You are being asked to take part in the research study named above because you are infected with the Human Immunodeficiency Virus (HIV), the virus that causes AIDS and are taking the HIV medicines, efavirenz or atazanavir/ritonavir/tenofovir or darunavir/cobicistat or atazanavir/cobicistat, and plan to start using an oral contraceptive pill containing ethinyl estradiol, or an etonogestrel implant after you deliver your baby.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

WHY IS THIS STUDY BEING DONE?

Some HIV medicines interact with hormonal birth control, potentially changing the levels of the birth control (increasing the chance of side effects or of pregnancy) or of the HIV drug (increasing side effects or decreasing HIV activity). We want to study whether oral contraceptive pills containing the estrogen agent ethinyl estradiol or the contraceptive etonogestrel implant have significant interactions with darunavir/cobicistat, atazanavir/cobicistat, efavirenz or atazanavir/ritonavir/tenofovir . We want to look at the levels of these medicines in your blood before you start one of the two types of hormonal birth control. Then we will measure the levels of these medicines again after you have been on birth control for several weeks and see if the levels have changed. We will also measure the levels of the hormones in your blood from the birth control and compare those levels to results from women using the same birth control but not taking antiretroviral medicines. We can see if the hormones and antiretroviral (ARV) medicines interact or not and see if hormonal birth control should work as well in women on certain ARV drugs. We will also look to see how safe these medicines are for you.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?

You will continue to obtain and take your HIV medicines as you would normally. No HIV medicines or hormonal contraceptives are supplied by this study. Your doctor will review with you any dietary recommendations related to the HIV medicines that you are taking. You will need to be on the same dose of your HIV medicines for at least 2 weeks before your first study visit.

2-12 weeks after you deliver your baby

You will need to come to the clinic to make sure you are eligible for the study before you enroll. This may be done as part of your first study visit, so a separate visit will not be required. We may test you for HIV to confirm your status. You will have a history and physical exam, and routine blood tests to see if it

is safe for you to be in the study. You will be asked about taking your HIV medicines. Blood will be drawn to check how well your body is able to fight infection and to check the amount of HIV in your blood. The total amount of blood taken from these tests will be 13 – 16 mL (about 2½ to 3 ½ teaspoons). You will be given the results of these tests. You will be asked to sign this consent form.

If you are able to be in this study, blood tests will be done to measure the amount of HIV medicine in your blood. A small plastic catheter (soft tube) will be placed in a vein in your arm and stay there for about a half a day so that blood can be drawn about 7 -8 times, without having to stick you more than about once. Depending on the medicine(s) you are taking, 7 blood samples over 12 hours, or 8 blood samples over 24 hours will be taken. The total amount of blood taken for these tests will be 17-19 mL (about 4 teaspoons). You will be asked to provide the times and amounts of your last two doses of medicine and last two meals. Before these blood samples are taken, the study staff will review with you any food recommendations related to the HIV medicines you are taking. After these blood tests are taken, you will start the oral contraceptive pills as prescribed by your regular doctor or have the etonogestrel implant inserted by your doctor.

6 to7 weeks after you have started hormonal contraceptives

You will come to the clinic 6-7 weeks after you have started hormonal contraceptives and the same tests that were done 2-12 weeks after you delivered your baby will be repeated. We will ask you questions about how you are taking your medicines. A pregnancy test will also be done. You will take your HIV medicine at the same time of day you take your hormonal contraceptives three days before you have repeat blood samples drawn and on the day you have repeat blood samples drawn to check the levels of hormone and HIV medicine in your blood. If you are using the etonogestrel implant 4mL (about one teaspoon) of blood will be taken from you. If you are using oral contraceptives eight (8) blood samples (about 3 teaspoons) will be taken over 24 hours. The total amount of blood taken for all these tests will be between 35-49 mL (about 7 to 10 teaspoons) depending on which contraceptive method you are using. This testing will be done in batches later in the study, so you and your doctor won't get the results of these tests until the end of the study. You will be asked about taking your HIV medicines.

Genetic Testing

Some of your blood collected for other tests will be used for genetic testing to help understand how your body handles your medications based on your genes and DNA. You may decide that you do not want your genes to be tested. Tell your health care provider if you decide this. You can still participate in this study even if you make this decision. This test will be done later in the study so you will not receive the results of this test. Please read the following statement carefully and then mark your initials in the appropriate space provided:

I agree to allow my DNA to be tested.

*Yes*_____ *No*_____ *Initials* _____ *Date* _____

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study will enroll 100 women; 25 women per HIV medicine/hormonal contraceptive combination.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study until 6-7 weeks after you start taking hormonal contraceptives.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?

The study doctor may need to take you off the study early without your permission if:

- The study is cancelled by the IMPAACT network, U.S. Food and Drug Administration (FDA), National Institutes of Health (NIH), the Office for Human Research Protections (OHRP), other local or national regulatory agencies, or the site's Institutional Review Board (IRB) or Ethics Committee. An IRB is a committee that watches over the safety and rights of research subjects.
- You are not able to attend the study visits as required by the study.
- You need a treatment that you may not take while on study.
- You are not able to take the HIV medicines or hormonal contraceptives required by the study.

If you must stop taking the study drug(s) before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

WHAT ARE THE RISKS OF THE STUDY?

The medicines used in this study may have side effects. Your doctor will explain the possible side effects of the medicines you are taking. If you have any questions concerning the possible side effects of the medicines that you are taking, please ask the medical staff at your site to review them with you.

Risks of Drawing Blood

You may feel faint or lightheaded or feel some discomfort when blood is drawn for this study. Other risks include bleeding or bruising where the needle enters the body. A small blood clot may form where the needle enters the body or swelling of the surrounding skin may occur. There is also a small risk of a minor infection at the blood draw site.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If you take part in this study, there may be no direct benefit to you but you will have more doctor visits where you can be checked for safety on your medications. Information learned from this study may help others who are taking HIV medicines and want to use hormonal contraceptives.

WHAT ABOUT CONFIDENTIALITY?

For US Sites
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the U.S. Food and Drug Administration (FDA).

People who may review your records include: the U.S. Food and Drug Administration (FDA), (insert Name of Site) IRB, National Institutes of Health (NIH), the Office for Human Research Protection, study staff, and study monitors. Any publication of this study will not use your name or identify you personally.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you or your participation in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate of Confidentiality to withhold that information.

(For sites outside the U.S.)
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Any publication of this study will not use your name of identify you personally.

Your records may be reviewed by the Ministry of Public Health in your country, the FDA, the Office of Human Research Protections (OHRP), the NIH, (*insert name of site)* IRB, Ethics Committee (EC), study staff, and study monitors.

WHAT ARE THE COSTS TO ME?

There is no cost for the study-related clinic visits, examinations, and laboratory tests in this study. Any medical costs for your treatment outside this study, including your prescribed HIV medicines or hormonal contraceptives will be charged to you or your health insurance company. This study will not cover any cost related to your pregnancy and delivery or care of your baby. You will not receive payment for your participation in this study.

WHAT HAPPENS IF I AM INJURED?

If you are injured as a result of being in this study, you will be given immediate treatment for your injuries. The cost for this treatment will be charged to you or your insurance company. There is no program for compensation either through this institution or the National Institutes of Health (NIH). You will not be giving up any of your legal rights by signing this consent form.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your decision will not have any impact on your participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are otherwise entitled.

We will tell you about new information from this or other studies that may affect your health, welfare or willingness to stay in this study. If you want the results of the study, let the study staffs know.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?

For questions about this study or a research-related injury, contact:

- name of the investigator or other study staff
- telephone number of above

For questions about your rights as a research subject, contact:

- name or title of person on the Institutional Review Board (IRB) or other organization appropriate for the site
- telephone number of above

SIGNATURE PAGE

If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

_____	_____
Participant's Name (print)	Participant's Signature and Date
_____	_____
Participant's Legal Guardian (print) (As appropriate)	Legal Guardian's Signature and Date
_____	_____
Study Staff Conducting	Study Staff Signature and Date
_____	_____
Witness' Name (print)	Witness's Signature and Date