

APPENDIX IV: SAMPLE INFORMED CONSENT FORMS

**DIVISION OF AIDS
HIV Prevention Trials Network (HPTN)
SAMPLE SCREENING INFORMED CONSENT FORM**

**HPTN 059
Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1%
Tenofovir Gel**

**Final Version
Version 2.0
13 March 2006**

**PRINCIPAL INVESTIGATOR: [insert]
PHONE: [insert]**

Short Title for the Study:

HPTN 059 Safety and Acceptability Study of 1% Tenofovir Gel

Introduction

You are being asked to take part in these screening exams and tests because you are a sexually active woman between the ages of 18 and 50, and you may be able to join the research study named above. This study is sponsored by the U.S. National Institutes of Health (NIH). The person in charge of this study at this site is [INSERT NAME OF PRINCIPAL INVESTIGATOR]. The screening exams and tests include interview questions, urine and blood tests, a physical exam, and an exam of your vagina.

This is a consent form. It gives you information about the screening exams and tests. The study staff will explain the exams and tests to you and what is expected of you. You are free to ask questions about the screening exams and tests at any time. If you agree to have the screening exams and tests, you will be asked to sign this consent form or make your mark in front of a witness. You will be offered a copy to keep.

Why Are These Screening Exams and tests Being Done?

The main purpose of these screening exams and tests is to find out if you can join a research study. The research study will try to find out if there are any bad effects when women apply tenofovir gel in the vagina for 24 weeks. About half of the women in the research study will insert the study gel into the vagina at bedtime every day. The other half of the women will insert the study gel into the vagina before having sex. The other purpose of the study is to find out what women think about the study gel.

Although tenofovir pills have been approved by the US Food and Drug Administration (FDA) for HIV treatment, the study gel is “experimental”. This means we do not know all the effects it may have. We do not know if it works to stop HIV from getting into the body. This is one of the reasons the study is being done. Because the study gel is experimental, the FDA and [LOCAL AUTHORITY] [HAS/HAVE] not approved it for use in the general community. The FDA has been informed of this study and has allowed it to happen. The [local authority] has also allowed the study to happen.

Before a large study can be done to find out if tenofovir gel stops HIV from getting into the body, we must first make sure it is safe. So far, the safety of the study gel has been tested among 84 women in the United States. They applied the gel in the vagina every day for two weeks. In that study, the gel was shown to be safe and women in the study did not have a lot of complaints or problems. The most common complaints were dryness, itching, burning, or pain in the genital area. Some women also complained that the gel leaked out of the vagina.

The United States National Institutes of Health is providing funds for this study to take place. A total of 200 women from Pune, India, Alabama, USA, and New York, USA, will join this study (100 in India and 100 in the US). About [INSERT EITHER – 100 or BETWEEN 50 AND 100] women will be in the study here at – [INSERT NAME OF SITE]. The whole study will take about one and half years to finish. Each woman will be in the study for about eight to twelve months. It will take about one week to two months to complete the screening exams and tests. It will take about six to nine months to complete the main study exams and tests. If you can join the study, you will be asked to use the study gel for six months. You will have a study visit every month for those six months.

Oral tenofovir is known to have an effect on the virus that causes hepatitis B virus. Participants with chronic hepatitis B will have extra tests to find out whether the tenofovir gel had an effect on their levels of hepatitis B. If you have chronic hepatitis B liver infection, after you have stopped using the study gel, you will be asked to return to the clinic for another three months. You will have a study visit every month for those three months for a blood test.

Some people may not be able to join the study because of information found during the screening exams and tests.

What Do I Have To Do If I Take Part in the Screening Exams and tests?

If you agree to have the screening exams and tests, you will have one or two screening visits here at the study site. The exams and test will take about one week to two months. Depending on what your screening exams and tests show, more screening visits may be needed. All screening exams and tests will be done within two months. If all exams and tests are not done within two months, and you still want to find out if you can join the research study, you will have to start the screening exams and tests over from the beginning.

Your first visit will continue today, after you read, discuss, and, sign or make your mark on this form. No study exams or tests will be started before the screening exams and tests have been fully explained to you and you have signed this form.

The visit will take about one to two hours.

To find out if you can join the study you will be asked some questions. The questions will be about you and where you live. You will be asked questions about your health, the medicine you take, your periods, and how you have sex. Some people may be embarrassed by questions about how they have sex.

If your answers to the questions show that you may join the study, you will have to give urine for a pregnancy test. You will receive the result of your pregnancy test today. If you are pregnant, you will not be able to join the study. However, site staff will talk to you about options available to you. They will refer you to available sources of medical care and other services you may need. If the study is still open after your pregnancy, you can come back here to find out if you can join the study then.

If you are not pregnant, study staff will talk to you about HIV and other sexually transmitted infections (STIs). You will have tests for HIV, gonorrhea, chlamydia, hepatitis B virus, syphilis, bacterial vaginosis, candidiasis, trichomonas, and herpes simplex virus. You will talk about HIV/AIDS and other STIs. You will also talk about ways that HIV and other STIs are spread, and ways to protect against them. You will talk about what it may mean to know the results of these tests. You can discuss whether you are prepared to receive the test results. If you are having health problems that may be due to STIs, the study staff will refer you for treatment or give you medicine to treat them.

It is not known if the study gel will work to protect against pregnancy, therefore you should not use the study gel as a birth control method. You must agree to use an effective method of birth control such as birth control pills or another hormonal based method (except for vaginal rings), an intrauterine device (or IUD), be sterilized, or have sex with a partner who is sterilized.

The study staff will provide condoms to you free of charge.

If you are willing to have HIV and STI testing, you will give blood (about 30 mL or two tablespoonfuls) [LOCAL EQUIVALENT - SITES TO COMPLETE] and urine for the tests. You must know what your HIV test says to join the study.

Your urine will also be tested for infections. Your blood will be tested for HIV. Your blood will also be tested to check on your general health, and the health of your liver, kidneys and blood. It takes about [X AMOUNT OF TIME - SITES TO COMPLETE] before your results are ready. We will give you your results as soon as they are ready.

You will have a physical exam and a pelvic exam. During the pelvic exam the study

doctor or nurse will use a speculum. A speculum is a plastic or metal instrument used to separate the walls of the vagina. It is used so that the study doctor or nurse can examine the vagina and the cervix during the exam. The part of the speculum that is inserted into the vagina looks a little like two spoons hinged together. With the speculum inside the vagina, the study doctor or nurse gently pushes the walls of the vagina apart by spreading the “spoons” away from each other.

Using the speculum makes it easier for the doctor or nurse to check the vagina and cervix. They will check for discharge, or other signs of infection, and other possible problems. The study doctor or nurse will also take some fluids to test for STIs and other possible problems.

If a sore (or other problem) is seen during the exam of your vagina, you may need medicine to treat it. You will be asked to see your regular health care provider for medicine or be given medicine here. We will ask you to come back here after a few days for another exam. If the sore (or other problem) has cleared up when you come back, you may be able to join the research study.

The study staff also will collect samples from your cervix to test for anything that is not normal. If the test is not normal, it could mean you have cervical cancer, or that it could lead to cervical cancer. This test is called a “Pap test”. It takes about [X AMOUNT OF TIME – SITES TO INSERT] before Pap test results are ready. We will give you the results as soon as they are ready. The results of your Pap test may affect whether you can use the study gel being tested in the research study.

It takes about [X AMOUNT OF TIME – SITES TO INSERT] before HIV and STI test results are ready. We will give you the results for all your exams and tests as soon as they are ready. You will talk with the study staff about the meaning of your test results and how you feel about them.

If your tests show that you have HIV you will not be able to join the study. The study staff will refer you to available sources of medical care and other services you may need for HIV. They will tell you about other studies that you may be able to join.

If your exams and tests show that you have an STI, you may need medicine to treat it. The study staff will refer you to your usual health care provider for medicine or give you medicine here to treat the STI. You will be asked to come back here after taking all the medicine. At that time, you will be able to enter the research study.

[SITES TO INCLUDE/AMEND THE FOLLOWING IF APPLICABLE:]

[LOCAL/STATE/NATIONAL] regulations require study staff to report the names of people who test positive for HIV and other infections passed during sex to the [LOCAL HEALTH AUTHORITY]. Outreach workers from the [health authority] may then contact you about informing your partners, since they also should be tested. If you do not want to inform

your partners yourself, the outreach workers will contact them, according to the confidentiality guidelines of the [HEALTH AUTHORITY].

If your exams and tests show no problems, you will be able to enter the research study. You will receive a different Informed Consent Form if you return for the Enrollment Visit.

If at any time during the screening it is found that you cannot join the study, the screening process and your visit will end.

Why Would The Doctor Stop the Screening Procedures Early?

The study doctor may need to stop the screening exams and tests early without your permission if:

- The study is cancelled by the U.S. Food and Drug Administration (FDA), U.S. National Institutes of Health (NIH), the drug company supporting this study, the Ethics Committees, the local government or regulatory agency, or the Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research subjects.)
- Your exams, tests and answers to the questions show you can not join the study.
- The study staff feels that having the screening exams and tests would be harmful to you.
- You do not want to find out your HIV test result.
- You are not able to come to the visits or complete the screening exams and tests.
- Other reasons that may prevent you from completing the study.

What Are The Risks Of The Study?

Risk of Blood Draws:

You may feel discomfort or pain when your blood is drawn. You may feel dizzy, faint or lightheaded. You may have a bruise, swelling, or infection where the needle goes into your arm.

Risk of Genital Exams:

You may feel discomfort or pressure during the exam of your genital area and inside your vagina. You may have mild vaginal spotting (bleeding). The mild bleeding will stop shortly after the exam.

Other Possible Risks:

You may become embarrassed, worried, or nervous when discussing how you have sex, ways to protect against HIV and other infections passed during sex, and your test results. You may become worried or nervous while waiting for your test results. If you have HIV or other infections, knowing this could make you worried or nervous. A trained counselor will help you deal with any feelings or questions you have.

We will make every effort to protect your privacy while you are having the screening exams and tests. Your visits here will take place in private. However, it is possible that others may learn that you are taking part in the study here. Because of this, they may treat you unfairly. For example, you could have problems getting or keeping a job, or being accepted by your family or community.

Are There Benefits To Taking Part In This Study?

You may get no direct benefit from the screening exams and tests. However, you will have a physical exam and a pelvic exam, and counseling and testing for HIV and STIs. You will also have tests to check your general health and the health of your liver, kidneys, and blood. This study can not provide you with medical care, but study staff will refer you to other available sources of care.

If your Pap test result is not normal, you will be referred for treatment at the [INSERT NAME OF PROVIDER/CENTER].

You will get counseling and testing for HIV. You will get free condoms. If you are infected with HIV, you will be referred for medical care, counseling, and other services available to you. Medical care for HIV infection will not be part of this study. You will need to get medical care for your HIV infection from your own health care provider. You will get counseling and testing for other infections. If you have these infections, you will be referred for treatment or get medicine to treat them here, if needed. You can bring your partner here for tests and treatment or referral for treatment for these infections if he needs them.

What Other Choices Do I Have Besides This Study?

You do not have to participate in this study, if you choose not to.

There are no gels known to protect against HIV during sex. **The only known way to protect against HIV during sex is to use a condom every time you have sex.**

[SITES TO INCLUDE/AMEND THE FOLLOWING IF APPLICABLE: There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish.]

Please talk to your doctor about these and other choices that may be available to you.

What About Confidentiality?

Efforts will be made to keep your personal information private. We cannot guarantee absolute confidentiality. Your personal information may be released if required by law.

If this study is published, your name will not be used and you will not be personally identified.

Your records may be reviewed by:

- The U.S. Food and Drug Administration (FDA)
- U.S. National Institutes of Health (NIH)
- The local government or regulatory agency
- [INSERT NAME OF SITE] IRB
- Study staff
- Study monitors
- Ethics committees
- Drug companies supporting this study

[FOR US SITES INSERT: The study staff will do everything they can to keep your personal information private, and they will have a Certificate of Confidentiality from the US Federal Government. This Certificate means that study staff cannot be forced to tell people who are not connected with the study, such as the court system, about your taking part in the study. The Certificate of Confidentiality does not prevent you from releasing information about yourself or your participation in the study. Even with the Certificate of Confidentiality, if the study staff learn of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.]

What Are The Costs To Me?

There is no cost to you for the screening exams and tests.

Will I Receive Any Payment?

You will be paid for your time and effort for each screening visit. You will receive [INSERT SITE - SPECIFIC AMOUNT OF MONEY] visits. You will also be paid for other costs to you for coming to the screening visits [SUCH AS CHILD CARE, TRAVEL, AND LOSS OF WORK TIME – SITES TO COMPLETE]. There may be one or more screening visits.

What Happens If I Am Injured?

It is unlikely that you will be injured as a result of having the screening exams and tests. If you are injured as a result of having the screening exams and tests, you will be given immediate treatment for your injuries. However, you may have to pay for this care. 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 U.S. National Institutes of Health (NIH). You will not be giving up any of your legal rights by signing this consent form.

[SITES TO SPECIFY INSTITUTIONAL POLICY]

What Are My Rights As A Research Subject?

Taking part in the screening exams and tests is completely voluntary. You may choose to not have the screening exams and tests any time. You will be treated the same no matter what you decide. If you choose to not have the screening exams and tests, you will not lose the benefit of services to which you would normally have at this clinic.

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 staff know.

What Do I Do If I have Problems or Questions?

For questions about the screening exams and tests or if you have a research-related injury, you should contact:

- [SITE INSERT NAME OF THE INVESTIGATOR OR OTHER STUDY STAFF]
- [SITE INSERT TELEPHONE NUMBER AND PHYSICAL ADDRESS OF ABOVE]

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

- [SITE INSERT NAME OR TITLE OF PERSON ON THE INSTITUTIONAL REVIEW BOARD (IRB) OR OTHER ORGANIZATION APPROPRIATE FOR THE SITE]
- [SITE INSERT TELEPHONE NUMBER AND PHYSICAL ADDRESS OF ABOVE]

SIGNATURE PAGE

[INSERT SIGNATURE BLOCKS AS REQUIRED BY LOCAL IRB/EC]

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

Participant's Name (print)

Participant's Signature and Date

Study staff Conducting
Consent Discussion (print)

Study staff Signature and Date

Witness' Name (print)
(As appropriate)

Witness's Signature and Date

DIVISION OF AIDS
HIV Prevention Trials Network (HPTN)
SAMPLE ENROLLMENT INFORMED CONSENT FORM
HPTN 059

**Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1%
Tenofovir Gel**

Final Version
Version 2.0
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PRINCIPAL INVESTIGATOR: [insert]
PHONE: [insert]

Short Title for the Study:

HPTN 059 Safety and Acceptability Study of 1% Tenofovir Gel

Introduction

You are being asked to take part in this research study because you are a sexually active woman between the ages of 18 and 50. This study is sponsored by the U.S. National Institutes of Health (NIH). The person in charge of this study at this site is [INSERT NAME OF PRINCIPAL INVESTIGATOR]. Before you decide if you want to join this study, we want you to know about the study.

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 or make your mark in front of a witness. You will be offered a copy to keep.

Why Is This Study Being Done?

The main purpose of the study is to see if there are any bad effects when women use tenofovir gel in the vagina for 24 weeks. About half of the women in the research study will insert the study gel into the vagina at bedtime every day; the other half of the women will insert the study gel into the vagina before sex. The other purpose of the study is to find out what women think about the study gel.

Although tenofovir pills have been approved by the FDA for HIV treatment, the study gel is “experimental”. This means we do not know all the effects it may have. We do not know if it works to stop HIV from getting into the body. This is one of the reasons the study is being done. Because the study gel is experimental, the FDA and [LOCAL AUTHORITY] [HAS/HAVE] not approved it for use in the general community. The FDA has been informed of this study and has allowed it to happen. The [LOCAL AUTHORITY] has also allowed the study to happen.

Before a large study can be done to find out if tenofovir gel protects against HIV, we must first make sure that it is safe. So far, the safety of the gel has been tested among 84 women in the United States who applied the gel in the vagina every day for two weeks. In that study, the gel was shown to be safe and women tested did not have a lot of complaints or problems with the gel. The most common complaints were dryness, itching, burning, or pain in the genital area. Some women also complained that the gel leaked out of the vagina.

It is not known if tenofovir gel will protect you from becoming infected with HIV. Therefore, you should not do anything that might expose you to HIV (such as unprotected sex or sharing needles for injection).

The United States National Institutes of Health is providing funds for this study to occur. A total of 200 women from Pune, India, Alabama, USA, and New York, USA, will take part in this study (100 in India and 100 in the US). About [INSERT NUMBER – 100 OR between 50 and 100] women will be in the study here at – [INSERT NAME OF SITE]. The whole study will take about one and half years to finish. Each woman will be in the study for about eight to twelve months. It will take about one week to two months to complete the screening exams and tests. If you can join the study, you will be asked to use the study gel for six months. If you have chronic hepatitis B, you will be asked to return to the clinic each month for three more months after you’ve stopped using the study gel for blood tests.

What Do I Have To Do If I Am In This Study?

If you decide to join this study, and your tests and answers to the questions show you can join, you will be placed in one of four study groups. Two groups will get tenofovir gel. Out of the two groups that get tenofovir gel, one group will apply the study gel once daily, and the other group will apply the study gel before sex. If you use the study gel with sex you will not use it more than twice a day. The other two groups will get a placebo gel. The placebo gel is a gel that looks and feels like tenofovir gel, and it is made up of all the same ingredients except tenofovir (the active ingredient). Out of the two groups that get the placebo gel, one group will use the study gel once daily, and the other group will use the study gel before sex but not more than twice a day. The study group will be chosen by chance, like flipping a coin, or throwing dice [SITE TO MODIFY TO LOCAL EQUIVALENT]. You cannot choose your group, and the study staff cannot choose your group for you. You have an equal chance of being placed in any one of the

groups. Neither you nor the study staff will know whether you are in the placebo or tenofovir groups.

All four groups are important to this study. No matter which study group you are in, you must remember that we do not know if any of the study gels work to protect women from getting HIV. The only known way to protect against getting HIV during sex is to use a condom every time you have sex.

It is not known if the study gel will work to protect against pregnancy, therefore you should not use the study gel as a birth control method. You must agree to use an effective method of birth control such as birth control pills or another hormonal based method (except for vaginal rings), an intrauterine device (or IUD), be sterilized, or have sex with a partner who is sterilized.

The study staff will provide condoms to you free of charge.

Each visit is described below. Your visits will not occur while you are having your period. You will insert into the vagina one applicatorful, about four grams (about one teaspoonful), of the study gel. One group of women will use the study gel at bedtime every day. The other group will use the study gel up to two hours before each act of vaginal sex, but not more than twice a day. You will use the study gel for 24 weeks. Once you join the study, you will return to the site for a follow up visit every four weeks for six visits.

After your six monthly visits, you will stop using the study gel. In total, you will have seven study visits including today's visit.

Oral tenofovir is known to have an effect on the virus that causes hepatitis B infection. Participants with chronic hepatitis B will have extra tests to find out whether the tenofovir gel had an effect on their levels of hepatitis B. If you have chronic hepatitis B, you will have the six monthly visits and an additional three monthly visits. The additional three monthly visits will occur during the three months after you have stopped using the study gel, for three months, for a total of ten study visits including today's visit.

After all the participants finish the study, and we find out the results of the study, if you wish, you will be told which study gel you received.

Final Screening/Enrollment Visit:

If you decide to take part in this study, your first visit will continue today, after you read, discuss and sign or make your mark on this form. No study procedures will be started before the visit exams and tests have been fully explained to you and you have signed this form. It will take about one hour.

To find out if you still can join the study you will be asked some questions - the

questions will be about you, where you live, and other questions about your health, your periods, the medicine you take, and your sexual practices. Some people may be embarrassed by questions about their sexual history. Many of these questions and blood and urine tests are the same as the ones at the Screening Visit.

If your answers to the questions show that you can join the study, you will:

- Give urine for a pregnancy test. You will be given your result for the pregnancy test today. If you are pregnant, you will not be able to join the study; however site staff will talk to you on options available to you, and will refer you to available sources of medical care and other services you may need. If the study is still open after your pregnancy, you can come back here to find out if you can join the study then.
- You will have a pelvic exam. The study doctor or nurse will use a speculum. A speculum is a plastic or metal instrument used to separate the walls of the vagina so that the study doctor or nurse can examine the vagina and the cervix. The part of the speculum that is inserted into the vagina looks a little like two spoons hinged together. With the speculum inside the vagina, the study doctor or nurse gently pushes the walls of the vagina apart by spreading the “spoons” away from each other. The doctor or nurse will check the vagina and cervix for discharge, or other signs of infection, and other possible problems. During the pelvic exam, the study doctor or nurse will look at your genital area and into your vagina through a lens called a colposcope. The lens works like a magnifying glass to help the nurse or doctor see anything that may not be normal. The lens will not be inside your body. They may take photos with a camera. The study doctor or nurse will also take some fluids to test for STIs and other possible problems.

If a sore (or other problem) is seen during the exam of your vagina, you may need medicine to treat it. You will be asked to see your regular health care provider for medicine or be given medicine here. We will ask you to come back here after a few days for another exam. If the sore (or other problem) has cleared up when you come back, you may be able to join the research study.

If your exams and tests show no problems today, you will be able to join the study. You will find out if you are in the group that uses the study gel once daily or the group that uses the study gel before sex, but not more than twice a day.

To make sure it is safe for you to use the study gel, you will give blood (about 30 mL or two tablespoons) [OR LOCAL EQUIVALENT - SITES TO INSERT] and urine for the following tests:

- An HIV test. You must receive your HIV test results again to remain in the study.
- A hepatitis B test
- STI testing and counseling
- Urine test for infections

- Blood tests to check the overall health of your blood cells, and the health of your liver and kidneys.

It takes about [X AMOUNT OF TIME – SITES TO INSERT] before HIV and STI tests and blood test results are ready. We will give you the results from all the exams and tests as soon as they are ready. You will talk with the study staff about the meaning of your test results and how you feel about them.

If your exams and tests show that you have an STI, the study staff will refer you to your regular health care provider. They may give you medicine here to treat the infections. You will be asked to come back here after taking all the medicine for a check-up. After the STI has been treated, you may then be able to join the study.

After the study staff determine that you qualify for the study, at your enrollment visit and your last visit, some of your blood will be frozen and kept at the clinic while you are in the study. If needed, they will test this blood later in the study to help check on your health. Your blood also may be sent to Johns Hopkins University in the United States. Johns Hopkins University will test your blood for HIV and compare their results with our results. This will make sure that the HIV test result is correct.

If you have hepatitis B you will:

- Give extra blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] to check the viral levels of the hepatitis infection. The study staff will give you the results of your tests [IN X AMOUNT OF TIME – SITES TO INSERT].
- If you agree, give extra blood (about another 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] for storage for future testing to see how the hepatitis virus responds to tenofovir. You will receive a different Informed Consent Form if you agree to give extra blood for future testing.

You will be given tubes of either tenofovir gel or placebo gel with applicators. You will also be given instructions on how to use them. You will receive condoms, and panty liners and/or menstrual pads.

In addition to your study visits, you will be asked to do the following:

- Use an effective method of contraception during the study.
- Contact the study doctor or nurse if you have any discomfort or medical problems.
- Tell the study staff about any medications you take while in the study.
- Agree to use study provided panty liners and/or menstrual pads for your period, or in case the study gel leaks out of the vagina. If you need a different kind other than the kind provided to you by the study, let the study staff know. You can use your own tampons during your period.

- Be willing to use the condoms the study staff will give you. You **must not** use spermicides or condoms lubricated with spermicides, during the study. If you need to use a different kind other than the ones provided to you by the study, let the study staff know.
- At your Month 5 visit, you will be asked to use the study gel the morning of that visit or at least 2 to six hours before your visit. You will be asked to do this regardless of if you are in the group that uses the study gel daily or in the group that uses the study gel every time you have sex.

You **must not** do the following during the entire time while in the study:

- Use intravenous drugs except for medical use.
- Take part in studies of other vaginal products or any drug or device study. Tell the study staff if you plan to join another study.
- Use other participants' study gel.
- Douche or otherwise clean the vagina, or insert other products into your vagina, two hours before and two hours after using the study gel (menstruating participants are allowed to use tampons as needed)

Follow Up Visits:

Each monthly visit will take about an hour. The visits will not be scheduled during your period. You will have the following routine procedures at your six monthly visits:

- Tell the study staff any updated information about your address, telephone number or other contact information.
- Tell the study staff if you had any medical problems or discomfort since your last visit.
- Talk to study staff about ways to prevent HIV and STIs.
- Tell the study staff any new information about your health or your periods.
- Tell the study staff about any medicines you are taking.
- Give urine for a pregnancy test. You will receive the results of your pregnancy test day of the visit.
- Will be provided with the study gel and pantyliners and/or menstrual pads, and, condoms with instructions on how to insert the study gel (except Month 6 visit).

Visits 1 and 3 (Months 1 and 3):

You will complete all of the regular monthly procedures plus:

- Answer questions about your use of the study gel.
- Tell the study staff your thoughts and opinions about the study gel.
- Have a pelvic exam with a speculum, and with a colposcopic lens.
- Give blood about 10 mL or two teaspoonsful) [OR LOCAL EQUIVALENT – SITE TO

INSERT]. We will check your blood for the overall health of your blood cells, and the health of your liver and kidneys, the study staff will give you the results of your tests [IN X AMOUNT OF TIME – SITES TO INSERT]. Your blood will also be checked to see if any of the study gel gets into your blood.

If you have hepatitis B at Visit 3 (Month 3) you will:

Give extra blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] to check the viral levels of the hepatitis infection. The study staff will give you the results of your tests [IN X AMOUNT OF TIME – SITES TO INSERT].

- If you agree, give extra blood (about another 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] for storage for future testing to see how the hepatitis virus responds to tenofovir. You will receive a different Informed Consent Form if you agree to give extra blood for future testing.

Visits 2, 4, and 5 (Months 2, 4, and 5)

You will:

- Have all the routine procedures.
- At the month 5 Visit, give blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] to check if any of the study gel has been absorbed into your blood.

At Visit 5 (Month 5) you will do the following procedure in addition to those mentioned above:

- Insert study gel two to six hours before your visit. All participants will be asked to do this whether you are in the group that uses the gel every day, or only with sex.
- Give blood to check if any of the study gel has been absorbed into your blood

Visit 6 (Month 6)

You will stop applying the study gel at this visit. You will complete all of the routine monthly procedures plus:

- Answer questions about your use of the study gel.
- Answer some questions about how you used the study gel, and your thoughts and opinions of the study gel.
- Have an HIV test.
- Have a hepatitis B test.
- Have STI tests.
- Have counseling about HIV and other STIs before your tests, and after your tests if needed.
- Talk about ways that HIV and other STIs are spread, and ways to protect against them.
- Have a pelvic exam with a speculum, and with a colposcopic lens.

- Give blood (about 30 mL or 2 tablespoonsful) [OR LOCAL EQUIVALENT – SITE TO INSERT] and urine for STI tests and infections
- Your blood will be checked for the overall health of your blood cells, and the health of you liver and kidneys

If you do not have hepatitis B at this visit you will:

- Answer some questions about your thoughts and opinions about the study and how easy or difficult it was to be in the study.

If you have hepatitis B you will:

- Give extra blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] to check the viral levels of the hepatitis infection.
- If you agree, give extra blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] for storage for future testing to see how the hepatitis virus responds to tenofovir.

The study site staff will give you your test results as soon as they are available. The results may be given to you by phone. If you give your permission, the study site staff can visit you at your home or a place in your community. If your HIV test results are positive, they will not be given to you over the phone. We will ask you to come back to the clinic or will visit you at your home or a place in your community.

After You Finish Using the Study gel:

During this study you may have a chance to take part in additional studies. If you choose not to take part in any of our additional studies, your participation in this study remains the same.

If you have any problems or concerns regarding your health after using the study gel, let the study staff know. You can contact the study site staff at any time after you have finished using the study gel. The study site staff may want to let the study sponsor about any serious problems you tell them about.

If you have hepatitis B:

Visits 7, 8 and 9 (Months 7, 8 and 9):

You will return to the site for an additional three visits and will:

- Tell the study staff information about your address, telephone number or other contact information.
- Tell the study staff if you had any medical problems or discomfort since your last

visit.

- Talk to study staff about ways to prevent HIV and STIs.
- Tell the study staff about your health or your periods.
- Tell the study staff about any medicines you are taking.
- Give blood (about 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT] to check your liver, and your hepatitis B virus levels to see if the hepatitis gets worse. The study staff will give you the results of your tests [IN X AMOUNT OF TIME – SITES TO INSERT].
- If you agree, give extra blood for storage for future testing. (about another 5 mL or 1 teaspoonful) [OR LOCAL EQUIVALENT – SITE TO INSERT]
- At month 9 only, answer some questions about your thoughts and opinions about the study and how easy or difficult it was to be in the study.

Any Time During The Study:

If the study staff think you may have become pregnant, you will give urine for a pregnancy test. Also, if you are having health problems that may be caused by infections passed during sex, you will:

- Have an exam of your genital area and inside your vagina.
- Give blood or urine to test for infections passed during sex.
- Get treatment for infections passed during sex if you need it.

You are asked to tell the study staff about any medical problems you have, especially genital problems. You can contact the study staff between regular visits to report these problems. The study staff will examine you as necessary. They will either provide or refer you for medical care that you may need.

If the staff find that a study gel is causing you problems, they may ask you to stop using the study gel, either for a short time or permanently. The study staff will ask you to stop using the study gel if you become pregnant or if you become infected with HIV. Even if you stop using the study gel, you will be asked to stay in the study and have your follow up visits. You will have some or all of the originally planned exams and tests that the study staff would like you to have to check on your health.

If you have an infection passed during sex that your partner also may have, you can bring him here for counseling and referral for treatment.

You can have extra counseling and testing for HIV if needed between regular visits. If you wish, your partner can have counseling with you. If you become infected with HIV, you can stay in the study but you cannot keep using the study gel.

The study staff will give you counseling and refer you to available sources of medical care and other services you may need.

At each study visit, the study staff will update information on where you live and how to keep in contact with you. They will use this information to remind you of scheduled visits. If you miss a visit, the study staff will try to contact you by [SITE-SPECIFIC METHODS]. If you give your permission, they also may visit your home to find you. They will try to reach you through the contact people that you list. If they talk to these people, they will not tell them why they are trying to reach you.

[SITES TO INCLUDE/AMEND THE FOLLOWING IF APPLICABLE:]

[LOCAL/STATE/NATIONAL] regulations require study staff to report the names of people who test positive for HIV and other infections passed during sex to the [LOCAL HEALTH AUTHORITY]. Outreach workers from the [health authority] may then contact you about informing your partners, since they also should be tested. If you do not want to inform your partners yourself, the outreach workers will contact them, according to the confidentiality guidelines of the [HEALTH AUTHORITY].

How Many Women Will Take Part In this Study?

About 200 women will take part in this study. About 100 women will be from New York and Alabama. About 100 women will be from India.

How Long Will I be In This Study?

You will be in this study about six to eight months. You will be asked to apply the study gel for 24 weeks. The total time you will be on the study, including the time to complete the screening exams and tests and the main study is eight to twelve months.

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 U.S. Food and Drug Administration (FDA), U.S. National Institutes of Health (NIH), the drug companies supporting this study, the Ethics Committee, the local government or regulatory agency, or the Institutional Review Board (IRB). (An IRB is a committee that watches over the safety and rights of research subjects.)
- Data and Safety Monitoring Board (DSMB) recommends that the study be stopped early (A DSMB is an outside group of experts who monitor the study)
- You do not want to find out your HIV test result.
- You are not able to keep appointments or apply study gel as instructed.
- Other reasons that may prevent you from completing the study successfully.

The study doctor will ask you to stop using the study gel but continue to come in for your follow up visits and procedures if:

- You are pregnant.
- You become infected with HIV.
- The study doctor decides that using the study gel would be harmful to you or your partner.
- You require a treatment that you may not take while using the study gel.
- You have a bad reaction to the study gel.

You will stop using the study gel until the study doctor decides it is safe for you to start using the study gel again, if possible.

What are the risks of this study?

Risks of Blood Draws:

When your blood is taken, you also may feel discomfort. You may feel dizzy, faint or lightheaded. You may have a bruise, swelling, or infection where the needle goes into your arm.

Risk of Genital Exams:

You may feel discomfort or pressure during the exam of your genital area and inside your vagina. You may have mild vaginal spotting (bleeding). The mild bleeding will stop shortly after the exam.

Other Possible Risks:

You may become embarrassed, worried, or nervous when discussing sexual behaviors and HIV. You may become worried or nervous while waiting for your STI and HIV test results. If you have HIV, knowing your HIV status could make you worried or nervous. You will talk with a trained staff member who will help you deal with any feelings or questions you have.

Risks of Tenofovir Gel:

It is very important to use the study gel as instructed by staff. The study gel used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known or possible relationship. If you have questions concerning additional study drug side effects please ask the study staff at your site.

Some of the effects of the tenofovir gel are still unknown. Some possible effects are dryness, itching, burning, or pain in the genital area. You may also have discharge if the study gel comes out of the vagina. The study staff will give you panty liners and/or menstrual pads in case you need them. In about half of the women tested before, there was a small amount of irritation in the genital area.

It is possible that tenofovir gel could be absorbed from the vagina into the blood. Based on the earlier study of tenofovir gel, a small amount (about 1% of the amount that is absorbed when the oral pill is taken) of tenofovir gel from the vagina was absorbed into the blood in about half of the women tested. If the gel is absorbed into the blood, it is not known whether this will cause any bad effects.

There are other side effects in patients taking the oral form (a pill) of tenofovir which is absorbed into the blood. However, these side effects may have been because of other medicines that patients were taking or because of the HIV itself. We are still learning about the gel, and some side effects may not be known.

The following side effects have been associated with the use of tenofovir pills:

- Upset stomach, vomiting, gas, loose or watery stools.
- Dizziness.
- Abdominal pain.
- Lack of energy.
- Kidney damage or failure.
- Inflammation or swelling and possible damage to the pancreas.
- Shortness of breath.
- Rash.
- Low phosphate, a chemical in the blood.
- Allergic reaction, which may include fever, rash, upset stomach, vomiting, loose or watery stools, abdominal pain, achiness, shortness of breath or a general feeling of illness.
- Changes in bone growth and strength were seen in study animals given tenofovir. It is unknown if long term use of topical tenofovir will cause bone abnormalities in adults. Bone thinning has been seen in adults and children taking oral tenofovir.

Laboratory tests have shown changes in the bones of patients treated with the pill form of tenofovir. An earlier study has shown that only a small amount of tenofovir gets into the blood with gel use. For that reason, the risk of changes to the bones when using the gel is low.

It is not known what effect tenofovir gel could have on the HIV virus. There is a small possibility that tenofovir could change the virus. If the virus changes normal treatment for HIV may not work on the virus. If you or your partner should become HIV positive during the study you should stop using the study gel immediately.

It is not known what effect tenofovir gel could have on the hepatitis B virus. There may be a risk that tenofovir will change the hepatitis B virus. If the virus changes normal treatment for hepatitis B may not work on the virus. It is not known what effect tenofovir gel could have on the disease condition in people with hepatitis B virus. It is possible

that if you have hepatitis B virus, it may become worse when you stop applying the study gel.

Possible Risks to Your Privacy

We will make every effort to protect your privacy while you are in this study. However, it is possible that you could have problems if people learn that you are in this study and think that you are infected with HIV or at risk of HIV because of sexual behavior or illegal drug use, or at high risk for HIV. Because of this, others may treat you unfairly. For example, you could have problems getting or keeping a job. You also could have problems being accepted by your family or community. There also is a risk to your privacy someone else in taking part in this study knows you.

Are There Risks Related To Pregnancy?

Because there is only a small amount of information on tenofovir in pregnant women, tenofovir should be used during pregnancy only if clearly needed. You must agree to try to not become pregnant during the study.

It is not known if the study gel used in this study harms unborn babies. You and your partner must be willing to use an effective method of birth control such as birth control pills or another hormonal based method (except for vaginal rings), an intrauterine device or IUD, be sterilized, or have sex with a partner who is sterilized. You should discuss this with the study staff. You must be willing to continue to use birth control for one month after you stop applying the study gel.

The study staff will provide condoms to you free of charge.

If you can become pregnant, you must have a pregnancy test before you enter this study. The test must show that you are not pregnant.

What If I Have A Positive Pregnancy Test During The Study?

If you think you may be pregnant at any time during the study, tell your study staff right away. The study staff will talk to you about your choices. If you have a positive pregnancy test while using the study gel, we will ask you to stop using the study gel, but will ask you to continue to be in the study and to come in for your follow up visits. There are no anticipated additional risks to you if you choose to continue to take part in this study.

We will ask you to return for another pregnancy test in six weeks (in addition to your next regularly scheduled visit). If your pregnancy test in six weeks is negative, you can start using the study gel again.

If you are pregnant, this study will not provide care related to your pregnancy, the delivery of your baby, or the care of the baby. Your baby may have been exposed to tenofovir if the study gel was absorbed from the vagina into your blood, and we do not know if this will affect unborn babies. The study staff will contact you to ask you a few questions about the

outcome of your pregnancy. You must arrange for your care and your baby's care outside of this study. The study staff will talk with you about care for your baby once he or she is born.

Breastfeeding

It is unknown if there are any effects of tenofovir gel on breast-milk. It is unlikely that the study gel will pass through breast milk but absorbing the study gel from the vagina into the blood may affect breast milk and may cause harm to your infant. You must agree to not breastfeed during this study.

Are There Benefits To Taking Part In This Study?

If you take part in this study, there may be no direct benefit to you because no one knows if the study gel will prevent HIV infection. Also, you may be in the study group that receives the placebo gel, which will not help in preventing HIV. Information learned from this study may help in the development of ways to prevent the spread of HIV in the future.

You will receive pelvic exams and counseling and testing for HIV and STIs. You will also have tests to check the overall health of your liver, kidneys, and blood cells. This study can not provide you with medical care, but study staff will refer you to other available sources of care.

If your Pap test result shows anything that is not normal, you will be referred for treatment at the [INSERT NAME OF PROVIDER/CENTER].

You will get counseling and testing for HIV. You will get free condoms. If you are infected with HIV, you will be referred for medical care, counseling, and other services available to you. Medical care for HIV infection will not be part of this study. You will need to get medical care for your HIV infection from your own health care provider. You will get counseling and testing for other infections. If you have these infections, you will get medicine to treat them, if needed. You can bring your partner here for tests and treatment for these infections if he needs them.

If you become infected with HIV during this study, you will be referred for medical care. Medical care for HIV infection will not be a part of this study. You will need to get medical care for your HIV infection from your own health care provider.

What Other Choices Do I Have Besides This Study?

You do not have to participate in this study, if you choose not to.

There are no gels known to protect against HIV during sex. **The only known way to protect against HIV during sex is to use a condom every time you have sex.**

[SITES TO INCLUDE/AMEND THE FOLLOWING IF APPLICABLE: There may be other studies going on here or in the community that you may be eligible for. If you wish, we will tell you about other studies that we know about. There also may be other places where you can go for HIV counseling and testing. We will tell you about those places if you wish.]

Please talk to your doctor about these and other choices that may be available to you.

What About Confidentiality?

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 or identify you personally.

Your records may be reviewed by:

- The U.S. Food and Drug Administration (FDA)
- U.S. National Institutes of Health (NIH)
- The local government or regulatory agency
- [INSERT NAME OF SITE] IRB
- Study staff
- Study monitors
- Ethics committees
- Drug companies supporting this study

[FOR US SITES INSERT: In addition to the efforts of the study staff to help keep your personal information private, a Certificate of Confidentiality has been obtained from the US Federal Government. This Certificate means that study staff cannot be forced to tell people who are not connected with the study, such as the court system, about your participation. The Certificate of Confidentiality does not prevent you from releasing information about yourself or your participation in the study. Even with the Certificate of Confidentiality, if the study staff learn of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.]

What Are The Costs To Me?

There is no cost to you for study related visits, study products, physical examinations, laboratory tests or other procedures.

Will I Receive Any Payment?

You will receive payment for your time and effort in this study. You will receive [INSERT SITE-SPECIFIC AMOUNT OF MONEY] visits. You will also receive payment for activities affected by your participation in this study [SUCH AS CHILD CARE, TRAVEL, LOSS OF WORK

TIME – SITES TO COMPLETE].

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. However, you or your insurance company may have to pay for this care. This institution or the U.S. National Institutes of Health (NIH) does not have a program to provide money for your injuries. You will not be giving up any of your legal rights by signing this consent form.

[SITES TO SPECIFY INSTITUTIONAL POLICY]

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. You will be treated the same no matter what you decide. If you choose not to participate or to leave the study, you will not lose the benefit of services to which you would otherwise be entitled at this clinic.

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 staff know.

What Do I Do If I have Problems or Questions?

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

- [SITE INSERT NAME OF THE INVESTIGATOR OR OTHER STUDY STAFF]
- [SITE INSERT TELEPHONE NUMBER AND PHYSICAL ADDRESS OF ABOVE]

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

- [SITE INSERT NAME OR TITLE OF PERSON ON THE INSTITUTIONAL REVIEW BOARD (IRB) OR OTHER ORGANIZATION APPROPRIATE FOR THE SITE]
- [SITE INSERT TELEPHONE NUMBER AND PHYSICAL ADDRESS OF ABOVE]

SIGNATURE PAGE

[INSERT SIGNATURE BLOCKS AS REQUIRED BY LOCAL IRB/EC]

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

Participant's Name (print)

Participant's Signature and Date

Study staff Conducting
Consent Discussion (print)

Study staff Signature and Date

Witness' Name (print)
(As appropriate)

Witness's Signature and Date

**DIVISION OF AIDS
HIV Prevention Trials Network (HPTN)
SAMPLE INFORMED CONSENT FORM FOR
THE STORAGE OF SPECIMENS OBTAINED WHILE PARTICIPATING IN
A DAIDS-SPONSORED RESEARCH TRIAL
FOR CHRONIC HEPATITIS B VIRUS INFECTED PARTICIPANTS**

**HPTN 059
Phase II Expanded Safety and Acceptability Study of the Vaginal Microbicide 1%
Tenofovir Gel**

**Final Version
Version 2.0
13 March 2006**

INTRODUCTION

You have decided to take part in a Division of AIDS research study. While you are in this research study there may be some samples of blood taken from you that might be useful for future research. You are being asked to agree to the storage of these samples. This consent form gives you information about the collection, storage and use of your samples. The study staff will talk with you about this information. Please ask any questions, if you have some. If you agree to the storage of your samples, you will be asked to sign this consent form. You will get a copy to keep.

HOW WILL YOU GET THE SAMPLES FROM ME?

The research doctors want to take extra blood samples from you during the study for storage. If you agree to these samples being taken, you will have about of blood (5 mL or one tablespoon) drawn [OR LOCAL EQUIVALENT - SITE TO SPECIFY] at the Final Screening/Enrollment Visit, and Monthly Visits 3, 6, 7, 8, and 9. These additional samples collected during the study will be kept and used for future research.

HOW WILL YOU USE MY SAMPLES?

Your samples will be used to look for evidence of the possible changes to the hepatitis B virus or damage caused by the infection, or your body's response to infection (such as examining cells, proteins, and other chemicals in your body) while you were using the study gel and after you stopped using the study gel. Tests may also include examining your genes (DNA), since they might affect your response to disease in important ways. Your genes might make you more or less susceptible to becoming infected, affect your responses to infection, or make your responses to treatment stronger or weaker. No other kinds of genetic test will be done by anyone on your stored specimens without first explaining the test to you and getting your permission.

The researchers do not plan to contact you or your regular doctor with any results from tests done on your stored samples. This is because research tests are often done with experimental procedures, so the results from one research study are generally not useful for making decisions on managing your health. Should a rare situation come up where the researchers decide that one of the test results would provide important information for your health, the researchers will notify your study doctor and your study doctor will try to contact you. If you wish to be contacted with this type of test result, you must give the study doctor or nurse any change to your address and/or phone number. If you want your regular doctor to be told about this type of test result, you must provide the study doctor or nurse with your regular doctor's name, address and phone number.

Your samples will not be sold or used directly to produce products that can be sold for profit. Research studies using your samples will be reviewed by the National Institutes of Health, and Ethics Committee, and a special committee at the researcher's institution (an Institutional Review Board).

HOW LONG WILL YOU KEEP MY SAMPLES?

There is no time limit on how long your samples will be stored.

HOW WILL MY SAMPLES BE STORED?

Your samples will be stored at special facilities that are designed to store samples safely and securely. The storage facilities are designed so that only approved researchers will have access to the samples. Some employees of the storage facilities will need to have some access to your samples in order to store them and to keep track of where they are, but these people will not have information that directly identifies you. An Institutional Review Board will oversee the storage facilities to protect you and other research volunteers from harm.

DOES STORAGE OF MY SAMPLES BENEFIT ME?

There are no direct benefits to you. The benefit of doing research on stored samples includes learning more about HBV infection.

WHAT ARE THE RISKS?

There are few risks related to storing your samples. When tests are done on the stored samples there is a small but possible risk to your privacy. It is possible that if others found out information about you that is learned from tests (such as information about your genes) it could cause you problems with your family (having a family member learn about a disease that may be passed on in families or learning who is the true parent of a child) or problems getting a job or insurance.

WHAT ABOUT CONFIDENTIALITY?

[Domestic Sites:] In order to keep your information private, your samples will be labeled with a code that can only be traced back to your research clinic. Your personal information (name, address, phone number) will be protected by the research clinic. When researchers are given your stored samples to study they will not be given your personal information. The results of future tests will not be included in your health records.

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have gotten a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with the research, such as the court system, about your participation. Also, any publication of the research will not use your name or identify you personally.

People who may review your records include: [INSERT NAME OF SITE] IRB, National Institutes of Health (NIH), study staff, study monitors, and their designees. Having a Certificate of Confidentiality does not prevent you from giving information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to you or others, we will tell the proper authorities.

Or

International Sites: In order to keep your information private, your samples will be labeled with a code that can only be traced back to your research clinic. Your personal information (name, address, phone number) will be protected by the research clinic. When researchers are given your stored samples to study they will not be given your personal information. The results of future tests will not be included in your health records. Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute privacy. Your personal information may be disclosed if required by law.

WHAT ARE MY RIGHTS?

Allowing your samples to be stored is completely voluntary. You may decide not to have any samples stored other than what is needed to complete this study and still be in this research study or any future study.

If you decide now that your samples can be stored for future research, you may change your mind at any time. You must contact your study doctor or nurse and let them know that you do not want your samples used for future research. Your samples will then not be used.

WHAT DO I DO IF I HAVE QUESTIONS?

For questions about the storage of your samples, contact (*insert the name of the investigator*) at (*insert telephone number*).

For questions about your rights related to the storage of your samples for research, contact (*insert the name or title of person on the Institutional Review Board*) at (*insert telephone number*).

[INSERT SIGNATURE BLOCK AS REQUIRED BY LOCAL IRB/EC]

Please carefully read the statements below and think about your choice. No matter what you decide it will not affect your care, or your ability to participate in the study.

I agree to have additional blood samples taken for the purpose of storage and testing for future research related to HIV and HBV infection.

_____ Yes

_____ No

Participant's Name

Participant's Signature

Date

Study staff Conducting
Consent Discussion

Study staff Signature

Date

Witness' Name
(As appropriate)

Witness' Signature

Date