

Partners HealthCare System Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: A phase 1 clinical trial to evaluate the safety and immunogenicity of an HIV-1 gp41 MPER-656 liposome vaccine in healthy, HIV-uninfected adult participants (HVTN 133)

Principal Investigator: [REDACTED]

Site Principal Investigator:

Description of Subject Population: Healthy, HIV-uninfected adult participants

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won’t change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

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Why is this research study being done?

In this research study we want to learn more about the safety of MPER-656 and how healthy people respond to it.

How long will you take part in this research study?

If you decide to join this research study, it will take you about 2 years to complete the study. During this time, we will ask you to make 13 study visits to Brigham and Women's Hospital.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen: we will take blood and urine samples, test your blood for HIV, do physical exams, ask you to fill out questionnaires, counsel you on how to reduce your risk of HIV, counsel you on how to reduce your risk of pregnancy, ask you about your health and medication, and give you MPER-656 or placebo.

Why might you choose to take part in this study?

You will not benefit from taking part in this research study. This study may help us develop an HIV vaccine in the future.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include redness and swelling. There may be others that we don't yet know about, even serious ones. We will tell you if we learn about any new side effects.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

The study vaccine may cause you to test positive on some types of HIV antibody tests, even if you do not have HIV. This is called vaccine-induced seropositivity (VISP). VISP means that after you get the study vaccine, a routine HIV test done outside this clinic may say you have HIV, even if you don't. For this reason, you should plan to get HIV tests only at this clinic

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during the study. Our tests can tell the difference between true HIV infection and a positive result that is caused by the study vaccine.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[REDACTED], MD is the person in charge of this research study. He can be reached 24 hours a day, 7 days a week at [REDACTED]. You can also call study staff at [REDACTED] Monday through Friday from 8:30am to 5:00pm with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call our study staff at [REDACTED].

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at [REDACTED].

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

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Detailed Information

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

The HIV Vaccine Trials Network (HVTN) and Brigham and Women's Hospital are doing a study to test an HIV vaccine. HIV is the virus that causes AIDS.

We are doing this study to answer several questions.

- Is the study vaccine safe to give to people?
- Are people able to take the study vaccine without becoming too uncomfortable?
- How do people's immune systems respond to the study vaccine? (Your immune system protects you from disease.)
- Does the vaccine have different effects at different doses?

Who will take part in this research?

About 24 healthy adults will take part in this study at multiple sites. About 20 people will take part at Brigham and Women's Hospital. The researcher in charge of this study at this clinic is [REDACTED], MD. The US National Institutes of Health (NIH) is paying for the study.

What will happen in this research study?

If you choose to take part in this research study, we will ask you to sign this consent form before we do any research study procedures. Take your time in deciding. If it helps, talk to people you trust, such as your doctor, friends, or family.

If you join this research study, you may not be allowed to join other HIV vaccine or HIV prevention studies now or in the future. You cannot be in this research study while you are in another research study where you receive a study product. Also, you should not donate blood or tissue during the research study.

As stated before, we will ask you to come in to the clinic for 13 scheduled study visits.

Screening Visit (Visit 1)

To see if you can take part in this research study, we will do some screening procedures and tests. The screening visit will take about 1 hour. The study doctor will review the results of these tests and procedures. If you do not qualify to take part in the research study, the study doctor will

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tell you why.

During the visit, we will:

- Do a physical exam.
- Ask you about your medical history and which medications you are taking.
- Ask you personal questions about your sexual activities and drug use.
- Draw blood samples to:
 - Test for HIV, hepatitis, and syphilis. If these tests show that you have HIV, hepatitis, or syphilis you cannot be in the study. We will refer you for medical care if we find you have any of these infections.
 - Check your immune response. The immune response is how the body protects itself from infection.
- Ask you for a urine sample to check the health of your kidneys.
- Do a urine pregnancy test, if you are a woman who is able to become pregnant. Pregnant or breastfeeding women cannot take part in this research study.
- Talk to you about how to avoid HIV infection (see below).

Drawing Blood

When we take blood, the amount at each visit will depend on the lab tests we need to do. It will be some amount between 10 mL and 340 mL (1 tablespoon to a little less than 1 and a half cups). Your body will make new blood to replace the blood we take out. To compare, people who donate blood in the US can give a total of about 500mL in an 8-week period.

Discussion about Avoiding HIV Infection

Throughout this research study, we will talk to you about how to continue to avoid HIV infection. We will ask you personal questions about your HIV risk factors, such as sexual behavior and drug use. We will talk with you about ways to keep your risk of getting HIV low. Some topics we may discuss include:

- What you think may be risky behavior for you.
- Ways to continue to avoid getting HIV.

These may include not having sex, using condoms, or behavior changes, such as moderate your alcohol consumption. We will talk with you about new methods of HIV prevention and can give you information on how to access them.

If you test positive for HIV, you will not be able to continue to in this research study. We will refer you for proper medical care.

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Reporting Positive Results of HIV, Hepatitis, and Syphilis Tests to Public Health Authorities:

As part of this research study, we will test you for hepatitis, syphilis, and HIV (the virus that causes AIDS). For most studies, this means that results will become part of your hospital medical record. If these tests show that you have hepatitis, syphilis, and/or HIV, we will refer you for medical care. By law, healthcare providers must report positive test results for specific infectious diseases to public health authorities, including the Massachusetts Department of Public Health. These reports are required to identify you by name.

What is MPER-656?

The study vaccine is called MPER-656 liposomes. From here on out, we will just call it the study vaccine or MPER-656.

The study vaccine has not been given to people before. It is an experimental HIV vaccine. That means we do not know if the study vaccine will be safe to use in people, or if it will work to prevent HIV infection.

The study vaccine has been tested in animals and appears safe. Even if something looks like it is safe or works in animals, it may not be true for people. The study vaccine is used only in research studies.

The study vaccine was developed by Duke University, working with the Infectious Disease Research Institute (IDRI). This study vaccine has man-made, short pieces of a protein called a peptide. This peptide looks like part of a protein found in HIV. The peptide in this study vaccine is combined with a tiny bit of fat called a liposome. The liposome helps keep the peptide in a shape that might make it easier for your immune system to respond to it. If you want to know more about the study vaccine, ask the study staff.

The study vaccine is mixed with an adjuvant. An adjuvant is a substance added to the vaccine to help the immune system respond better. The adjuvant in this study is called aluminum hydroxide or alum. Aluminum has been used in vaccines for more than 60 years.

Enrollment and Assignment to Study Group (Study Visit 2)

If you are still eligible for the study, you will be assigned to be in one of 2 groups. Each group will differ in what dose of MPER-656 they receive. Group 1 will receive a low dose of the study vaccine, and Group 2 will receive a higher dose. Group 1 will be enrolled first.

In each group, some people will get a placebo (sterile salt water). Which group you are in is completely random, like flipping a coin. You have a 5 in 6 chance of getting the study vaccine. Whether you get the study vaccine or the placebo is also random. We have no say in which group you are assigned to. Neither you nor we can change what group you are in once you are assigned to it. You will have to wait until everyone completes their final study visits to find out

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whether you got the study vaccine or the placebo. This could be several years. If you have a serious medical problem and need to know what you got before the end of the study, we can tell you.

		Injection Schedule			
	Group	First injection	2 months	6 months	12 months
5 people	1 Low dose	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant
1 person		Placebo	Placebo	Placebo	Placebo
15 people	2 Higher dose	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant	MPER-656 with alum adjuvant
3 people		Placebo	Placebo	Placebo	Placebo

Total: 24 people (20 study vaccine recipients and 4 placebo recipients)

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Receiving the Study Vaccines

For an intramuscular (IM) injection, a sterile needle is put directly into your deltoid (upper arm) muscle. You will get two injections at each injection visit, one in each arm. You can ask the study staff more about this. You will have to wait in the clinic for about half an hour after each injection to see if there are any problems.

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Study Diary

We will give you a study diary to fill out for 7 days after each study injection. You will need to write down how you are feeling and if you have any symptoms. Contact the study staff if you have any issues or concerns. If you have a problem, we will continue to check on you until it goes away.

Study Visits 2, 4, 6, 9

These visits will take about 3 hours. At each visit, we will:

- Give you the study products
- Check for any changes in your health since the last visit.
- Ask you how you are feeling, and if you are taking any medications.
- Perform a physical exam.
- Draw a blood sample (visits 2, 6, and 9)
- Test your urine for pregnancy, if you are of able to get pregnant.
- Ask you questions about any personal problems you may be having related to the study.
- Ask if there are any benefits from being in the research study.
- Ask you about your beliefs about getting outside HIV testing (visit 6).
- Test you for HIV (visits 6 and 9). The study doctor or a member of the study staff will talk with you about the test and your results.
- Counsel you on how to reduce your risk of getting HIV.
- Ask you about any vaccinations you may have received since your last visit.
- Ask you personal questions about your sexual behavior and any drug use (visits 6 and 9)

Follow Up Visits

Study Visits 3, 5, 7, 8, 10-12

Each study visit will last about 30 minutes. At each visit, we will:

- Check for any changes in your health since the last visit.
- Ask you how you are feeling, and if you are taking any medications.
- Perform a physical exam.
- Draw a blood sample.
- Test your blood for HIV (visits 5, 8, and 12)
- Collect a urine sample (visits 3 and 11)
- Do a urine pregnancy test (visit 11)
- Ask you questions about any personal problems you may be having related to the study (visit 12).
- Counsel you on how to reduce your risk of getting HIV.
- Ask you about any vaccinations you may have received since your last visit.
- Ask you personal questions about your sexual behavior and any drug use (visit 12).
- Ask you about your beliefs about getting outside HIV testing (visit 12).

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Final Contact (Study Visit 13)

This visit will take about 10 minutes. At this visit, we will ask you how you are feeling. You may not need to return to the clinic for this visit.

Stopping the Study Early

You are free to leave the research study at any time and for any reason. If you decide to leave this research study, please tell the study staff. We will ask you to come back to the clinic at least once.

This visit will take about 1 hour. At this visit we may:

- Perform a physical exam.
- Draw a blood sample.
- Collect a urine sample.
- Do a urine pregnancy test if you are a woman who can become pregnant.
- Test you for HIV. The study doctor or a member of the study staff will talk with you about the test and your results.
- Ask you questions to see if you have experienced personal problems or discrimination because you are in an HIV prevention study.

Also, we may stop your study injections or take you out of the study at any time. We may do this even if you want to stay in the study and even if you were scheduled for additional study injections. This may happen if:

- You do not follow instructions for this study.
- You are unwilling to take part in HIV risk reduction counseling.
- You get infected with HIV.
- You enroll in a different research study where you receive another study product.
- You need treatment for a medical problem, and the treatment and the study product might interfere with each other.
- You become pregnant.
- The researcher or your private doctor thinks that staying in the study might harm you.
- The study is stopped for any reason.

If we stop your study injections, we may ask you to stay in the research study to complete other study procedures.

If you become pregnant during the research study, we will ask you to continue to have some procedures including blood draws; however, no more than 50 mL (or a little more than 3 tablespoons) of blood will be taken within any 8-week period. You will not receive any more study injections while you are pregnant or breast-feeding. We will do this for as long as it is safe for you and your developing baby.

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If you leave the research study while you are still pregnant, we will contact you after your due date to ask some questions about your pregnancy and delivery.

How will we test your samples for this study?

The HVTN will test your samples to see how your immune system responds to the study products. We will send your samples (without your name) to labs approved by the HVTN for this study, which are located in the United States. In rare cases, some of your samples may be sent to labs approved by the HVTN in other countries for research related to this study.

Researchers may also do genetic testing related to this study on your samples. Your genes are passed to you from your birth parents. They affect how you look and how your body works. The differences in people's genes can help explain why some people get a disease while others do not. The genetic testing will only involve some of your genes, not all of your genes (your genome). The researchers will study only the genes related to the immune system and HIV and those that affect how people get HIV.

If you get HIV, the researchers may look at all of the genes of the virus found in your samples. The researchers will use this information to learn more about HIV and the study product(s). In some cases, researchers may take cells from your samples and grow more of them over time, so that they can continue to contribute to this study.

These tests done on your samples are for research purposes, not to check your health. The labs will not give the results to you or this clinic because their tests are not approved for use in making health care decisions. These labs are only approved to do research tests.

When your samples are no longer needed for this study, the HVTN will continue to store them.

How may we use and share your samples and health information for other research?

When samples are no longer needed for this study, the HVTN wants to use them in other studies and share them with other researchers. The HVTN calls these samples "extra samples." The HVTN will only allow your extra samples to be used in other studies if you agree to this. You will mark your decision on this form. You can change your mind at any time. If you no longer want to have your extra samples used, at your request, we will destroy all samples that we have. Your decision will not affect your being in this research study or have any negative consequences here.

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The extra samples are stored in a secure central place called a repository. Your samples will be stored in the HVTN repository in the United States. There is no limit on how long your extra samples will be stored.

A researcher may make a new scientific discovery or product based on the use of your samples. If this happens, there is no plan to share any money with you. The research is not likely to ever know who you are.

You will not benefit from letting us use your extra samples for other research. Results from these other studies will not be given to you, this clinic, or your doctor. They will not be used for your medical care and the results will not be placed in your medical record. The studies are only being done for research purposes.

The HVTN will not sell your samples or information; however, they may share your samples with other researchers. Once we share your samples and information, we will not be able to get them back. When a researcher wants to use your samples and/or information, their research plan must be approved by the HVTN. Also, the researcher's institutional review board (IRB) or ethics committee (EC) will review their plan. IRBs/ECs protect the rights and well-being of people in research. If the research plan is approved, the HVTN will send your samples to the researcher's location.

Your samples and information will be labeled with a code number. Your name will not be part of the information. However, some information that we share may be personal, such as your race, ethnicity, gender, health information from the research study, and HIV status. We may share information about the study product you received and how your body responded to the study product. The other studies that may be done will be related to HIV prevention or infection, the immune system and other diseases.

Researchers may also do genetic testing on your samples.

In some cases, researchers may take cells from your samples and grow more of them over time, so that they can continue to do research with them.

If you agree, your samples could also be used for genome wide studies. In these studies, researchers will look at all of your genes (your genome). The researchers compare the genomes of many people, looking for common patterns of genes that could help them understand diseases. The researchers may put the information from the genome-wide studies into a protected database so that other researchers can access it, but your name and other personal information will not be included. Usually, no one would be able to look at your genome and link it to you as a person. However, if another database exists that also has information on your genome and your name,

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someone might be able to compare the databases and identify you. If others found out, it could lead to discrimination or other problems. The risk of this happening is very small. There may be other unknown risks.

People who may see your information are:

- Researchers who use your extra samples and information for other research,
- Government agencies that fund or monitor (check) the research using your samples or information,
- Any regulatory agency that reviews clinical trials,
- The researcher's IRB or EC, and
- The people who work with the researcher.

All of these people will do their best to protect your information. The results of any new studies that use your extra samples or information may be published. No publication will use your name or identify you personally.

Whatever you choose, the HVTN will keep track of your decision about how your samples and information can be used. You can change your mind after signing this form.

Do you agree to let us store your extra samples for future research?

Please write your initials or make your mark in the box next to the option you choose.

YES. I allow my extra samples and information to be used for other studies related to HIV, vaccines, the immune system, and other diseases. This may include genetic testing and keeping my cells growing over time.

OR

YES. I agree to the above option *and* also to allow my extra samples and information to be used in genome wide studies.

OR

NO. I do not allow my extra samples to be used in any other studies. This includes not allowing genetic testing, growing more of my cells, or genome wide studies.

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Will you get the results of this research study?

- ▶ If the study sponsor gives us general information about the results of the research study to share with you, we will do so.
- ▶ Generally, we will not give you or your doctor information about the results of your individual participation in the research study. The research we are doing is only a stepping stone in understanding HIV vaccines. Most of the findings that come from studying your samples or information will not be relevant to your personal health. However, in the future, this may change.
- ▶ It is important to remember that research results are not always meaningful and are not the same as clinical tests. While you should not expect to get any information about the results of your participation in this research, if experts from the study decide that research results from your samples are of high medical importance, we will attempt to contact you. In some situations, follow-up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these follow-up tests and any follow-up care, including deductibles and co-payments.
- ▶ It is possible that you will never be contacted with individual research results. This does not mean that you don't have or won't develop an important health problem.

What are the risks and possible discomforts from being in this research study?

General risks of vaccines:

All vaccines can cause fever, chills, rash, aches and pains, nausea, headache, dizziness, and feeling tired. Vaccines can also cause pain, redness, swelling, or itching where you got the injection. Most people can still do their planned activities after getting a vaccine. Rarely, people have side effects that limit their normal activities or make them go to the doctor.

Rarely, a vaccine can cause an allergic reaction, including a rash, hives, or trouble breathing. Allergic reactions can be life-threatening. You should tell us if you have ever had a bad reaction to any injection or vaccine.

Very rarely, a vaccine causes an autoimmune disease in a person, or makes an autoimmune disease worse. An autoimmune disease happens when your immune system attacks your own body, instead of attacking an infection.

Risks of HIV vaccines:

We do not know if the study vaccine will increase, decrease, or not change your risk of getting HIV if exposed. If you get HIV, we do not know how the study vaccine might affect your HIV infection or how long it takes to develop AIDS.

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We do not know if getting this study vaccine will affect how you respond to any future approved HIV vaccine. Currently, no HIV vaccine has been approved for use

Risks of the study vaccine:

This section lists the side effects we know about. There may be others that we don't yet know about, even serious ones. We will tell you if we learn about any new side effects.

After getting the study vaccine, you could make antibodies that recognize parts of cells in humans. These are called autoantibodies. In animal studies, these autoantibodies did not show effects on the health of the animals.

Liposomes have been used for decades in cancer vaccines, animal vaccines, and drug treatments. When injected, liposomes can cause symptoms like other vaccines. The most common are redness and swelling where you got the injection and fever.

The adjuvant, alum, is the most widely used vaccine adjuvant. It has been used in licensed vaccines given to hundreds of millions of people all over the world. People can have the same kinds of side effects from the adjuvant as they do with vaccines, such as pain where they got the injection, muscle aches, or a fever.

Risks of giving blood and receiving injections:

In this study, we will do some routine medical procedures. These are taking blood and giving injections. These procedures can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, and (rarely) muscle damage or infection where you got the injection. Giving blood can cause a low blood cell count (anemia), making you feel tired.

HIV testing:

The body makes antibodies to fight or prevent infection. Most vaccines cause the body to make antibodies as a way of preventing infection. Your body may make antibodies to HIV because you received an HIV study vaccine. The study vaccine may cause you to test positive on some types of HIV antibody tests, even if you do not have HIV. This is called vaccine-induced seropositivity (VISP). VISP means that after you get the study vaccine, a routine HIV test done outside this clinic may say you have HIV, even if you don't. For this reason, you should plan to get HIV tests only at this clinic during the study. Our tests can tell the difference between true HIV infection and a positive result that is caused by the study vaccine.

If you have a positive test result caused by the study vaccine at any time, we can arrange free HIV testing for as long as you need it. If this happens, we do not know how long you will test positive due to the study vaccine. If you receive a positive HIV test result and we determine it is because you have HIV, we will refer you for follow-up care.

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It is unlikely, but you could test negative at the end of the study and positive some time later, even though you don't have HIV. This could happen if different HIV tests come into use. We will give you a phone number to call for more information.

If someone believes you have HIV even if you do not, you could face discrimination and other problems. For example, in some countries, you could be denied medical or dental care, employment, insurance, a visa, or entry into the military. If you do have a positive HIV antibody test caused by the study vaccine, you will not be able to donate blood or organs. Your family and friends may treat you differently. We will give you a brochure that tells you more about testing HIV positive because of an HIV vaccine, and how you can avoid some of these problems. If you become pregnant during or after the study and have VISP, we don't know if the antibodies could be passed to your baby. We know that this happens with other vaccines, like tetanus vaccine. These antibodies from the mother are not a danger to the baby, and they go away over time. For most babies' antibodies from the mother last for about six months.

You should always tell the delivery staff if you have VISP. However, you may still be tested for HIV using the antibody test when you deliver your baby. If your test is positive and the delivery staff believes you have HIV, your baby may be started on antiretroviral treatment when it is not needed. If this happens, we can arrange for you and the baby to have a test that can tell the difference between true HIV infection and a VISP result. If you or the baby continue to have VISP, we can arrange this testing for free for as long as it is needed.

Embarrassment/anxiety:

You may feel embarrassed when we ask about your HIV risks, such as having sex and using drugs. Also, waiting for your HIV test results or other health test results could make you feel anxious. You could feel worried if your test results show that you are infected with HIV. If you feel embarrassed or anxious, please tell us and we will try to help you.

Risks of genetic testing:

The genetic testing could show you may be at risk for certain diseases. If others found out, it could lead to discrimination or other problems. However, it is almost impossible for you or others to know your test results from the genetic testing. The results are not part of your study records and are not given to you.

In the very unlikely event that your genetic information becomes linked to your name, a federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you. GINA keeps health insurance companies and employers from seeing results of genetic testing when deciding about giving you health insurance or offering you work. GINA does not help or protect you against discrimination by companies that sell life, disability or long-term care insurance.

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Risks to an Embryo or Fetus, or to a Breastfeeding Infant:

You should not become pregnant during the study because we do not know how the study vaccine could affect the developing baby. You must agree to use effective birth control from 21 days before your first injection through your last scheduled clinic visit. We will talk to you about effective birth control methods. Because of these unknown risks, you cannot take part in this study if you are:

- Pregnant,
- Trying to become pregnant,
- Or breastfeeding.

Although taking testosterone can lower the chances of becoming pregnant, it is not considered an effective method of birth control. Effective birth control means using any of the following methods every time you have sex:

- Drugs that are prescribed specifically for birth control and intended to prevent pregnancy—these include pills, shots, patches, vaginal rings, or inserts under the skin;
- Male or female condoms, with or without a cream or gel that kills sperm;
- Diaphragm or cervical cap with a cream or gel that kills sperm;
- Intrauterine device (IUD); or
- Any other contraceptive method approved by the researchers.

You do not have to use birth control if:

- You have had a hysterectomy (your uterus removed);
- You have had your ovaries removed
- You are only having sex with a partner or partners who have had a vasectomy. (We will ask you some questions to confirm that the vasectomy was successful.);
- You have a tubal ligation (your “tubes tied”) or confirmed successful placement of a product that blocks the fallopian tubes; or
- You are sexually abstinent (no sex at all).

If you are menopausal and have not had a period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. The documented methods of surgical sterilization include having had a hysterectomy (removal of the uterus with or without the ovaries), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), or transvaginal occlusion (plugging the opening of the tubes with a coil).

If you are capable of becoming pregnant and decide to join the study, we will test you for pregnancy at some visits, including before each study injection.

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Risks of disclosure of your personal information:

We will take several steps to protect your personal information. Although the risk is very low, it is possible that your personal information could be given to someone who should not have it. If that happened, you could face discrimination, stress, and embarrassment. We can tell you more about how we will protect your personal information if you would like it.

What are the possible benefits from being in this research study?

We do not expect the study vaccine to benefit you in any way. However, being in the study might still help you in some ways. The counseling that you get as part of the study may help you avoid getting HIV. The lab tests and physical exams that you get while in this study might detect health problems you don't yet know about.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

We will pay you \$850 if you complete this research study. If you do not complete the study, we will pay you \$50 for each follow-up study visit or \$100 for each injection visit you complete in person. We will not pay you for phone, email, or text message contact.

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You will also not receive any money if you decide to donate your extra samples or information for other research, even if this research leads to a new discovery.

We will pay for reasonable roundtrip transportation expenses when you come in for study visits. We will ask you to save your receipts for your travel expenses and give the receipts to us so we can pay you. We will provide you with vouchers (coupons) to pay for your parking in the hospital garage during study visits.

Payments you receive for being in the study may be considered taxable income. If we pay you more than \$600 between January 1 and December 31 of the same year, the study doctor will have to report this to the Internal Revenue Service (IRS). This will be reported using a 1099 (Miscellaneous Income) form. This form will be issued to you and a copy will be sent to the IRS. The clinic staff may need to ask you for your Social Security Number or Tax Identification Number to complete the report.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

The study injections, study visits, examinations, laboratory tests, and all the other procedures that are done only for the research will be paid for by the study funds. You do not have to pay anything to be in this study.

Charges for any ongoing or routine medical care you receive outside this research study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

What happens if you are injured as a result of taking part in this research study?

Your health is important to us. If you become sick or injured in this study, there is a process to decide if it is related to the study vaccine and/or procedures. If it is, we call it a study-related injury. There are funds to pay for treatment of study-related injuries if certain conditions are met. The study product provider may agree to pay medical costs for study-related injuries that are determined to be caused by the study product

The HVTN has limited funds to pay medical costs that it determines are reasonable. If the injury is not study related, then you and your health insurance will be responsible for treatment costs.

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Some injuries are not physical. For example, you might be harmed emotionally by being in an HIV vaccine study. Or you might lose wages because you cannot go to work. However, there are no funds to pay for these kinds of injuries, even if they are study related.

You may disagree with the decision about whether your injury is study related. If you wish, the HVTN will ask independent experts to review the decision. You always have the right to use the court system if you are not satisfied.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)

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- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

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The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

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Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

Subject

Date

Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date

Time (optional)

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