Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: [redacted] MD **Revision Date**: 4.23.19
Study Title: A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1–uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells (HVTN 123, Version 1)
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to healthy volunteers

Name of participant: _____ Age: _____

Thank you for your interest in our research study. Please read this consent form or ask someone to read it to you. If you decide to join the study, we will ask you to sign or make your mark on this form. You will be given a copy of this consent form to keep. We will ask you questions to see if we have explained everything clearly. You can also ask us questions about the study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

About the study

The HIV Vaccine Trials Network (HVTN) and Vanderbilt University Medical Center are doing a study to test HIV vaccines. HIV is the virus that causes AIDS.

About 30 people will take part in this study at multiple sites. We would like to enroll approximately 15 people in this study at Vanderbilt University. The researcher in charge of this study at this clinic is Dr. [redacted] The US National Institutes of Health (NIH) is paying for the study.

1. **We are doing this study to answer several questions.**
   - Are the study vaccines safe to give to people?
   - Are people able to take the study vaccines without becoming too uncomfortable?
   - How do people's immune systems respond to the study vaccines? (Your immune system protects you from disease.)
   - Does a small difference in the way the 2 vaccines were made change how people's immune systems respond?

2. **The study vaccine cannot give you HIV.**

The study vaccines are not made from actual HIV. It is impossible for the study vaccines to give you HIV. Also, they cannot cause you to give HIV to someone else.

3. We do not know if the study vaccines will decrease, increase, or not change your risk of becoming infected with HIV if you are exposed to the virus.

Several studies have tested whether HIV vaccines can reduce the risk of getting HIV from another person. In some studies, people who got the vaccine seemed to have the *same* risk of getting HIV as people who did not get the vaccine. In one study, people who got the vaccine seemed to have a *lower* risk of getting HIV than people who did not get the vaccine. In studies with a different vaccine, some people who got the vaccine had a *higher* risk of getting HIV than people who did not get the vaccine.

This study differs from the studies in which people who got the vaccine had a higher or lower risk of getting HIV. We can tell you about the differences.

We do not know whether the vaccine in this study will affect your risk of getting HIV from another person. The risk could be higher, lower, or unchanged. It's very important to avoid exposure to HIV during and after the study. We will tell you how to avoid HIV.

4. These study vaccines are experimental.

The study vaccines are protein vaccines called Stable CH505TF gp120 and Transient CH505TF gp120. From here on, we will call them gp120S and gp120T study vaccines. They are experimental HIV vaccines. That means we do not know if the vaccines will be safe to use in people, or if they will work to prevent HIV infection. These vaccines are used only in research studies.

For both vaccines, first DNA is used in a lab to tell cells how to make the protein. The gp120S vaccine was made by having the DNA that makes the protein become a part of the DNA of the cell. For the gp120T vaccine, the DNA that makes the protein was put into the cells, but did not become a part of the cell's DNA. In both cases, after the protein is made, it is separated from the cells and purified into a vaccine.

The vaccines were developed by the Division of AIDS (DAIDS) at the National Institutes of Health (NIH). The vaccines have man-made pieces of protein that look like part of the protein found in HIV. Your body's immune system might learn to recognize these proteins and prepare itself to fight HIV. This is called an immune response.

The vaccines are 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 GLA-SE. GLA-SE was made by Infectious Disease Research Institute (Seattle, Washington, USA).

The gp120S and gp120T vaccines are very similar protein vaccines made in the laboratory in two slightly different ways.

The gp120S study vaccine has been tested in animals and it did not cause any health concerns. Animal testing may not always tell us what will happen with humans. It has been given to about 42 people in another study

that is ongoing and has not caused serious health problems. If we learn anything from that study that might affect your participation in this study, we will tell you.

The gp120T study vaccine has not been given to people before. Similar vaccines to those being used in this study have been given to thousands of people and have not caused serious health problems.

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 the study vaccines:

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.

The gp120S vaccine with the GLA-SE adjuvant has been given to a small number of people in a study that is still going on. The most common complaints have been pain or tenderness where they got the injection. One person had a skin infection where they got the injection. It did not affect that person's daily routine. That person took some medicine and it got better within 5 days.

The gp120T study vaccine has not been given to people before.

The adjuvant, GLA-SE, has also been tested in over 900 people with vaccines for other diseases. The most common complaints were pain and tenderness where they got the injection and feeling tired.

Joining the Study

5. It is completely up to you whether or not to join the study.

Take your time in deciding. If it helps, talk to people you trust, such as your doctor, friends or family. If you decide not to join this study, or if you leave it after you have joined, your other care at this clinic and the benefits or rights you would normally have will not be affected.

If you join this 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 study while you are in another study where you get a study product. Being in more than one study may not be safe.

Also during the study, you should not donate blood or tissue.

If you choose not to join this study, you may be able to join another study.

6. If you want to join the study, we will screen you to see if you are eligible.

Screening involves a physical exam, HIV test and health history. A physical exam may include, but is not limited to:

- Checking your weight, temperature and blood pressure
- Looking in your mouth and throat
- Listening to your heart and lungs
- Feeling your abdomen (stomach and liver)

We will also do blood and urine tests. These tests tell us about some aspects of your health, such as how healthy your kidneys, liver, and immune system are. We will also test you for: Hepatitis B, Hepatitis C and syphilis. We will ask you about medications you are taking. We will ask you about behaviors that might put you at risk for getting HIV. If you were assigned female sex at birth, we will test you for pregnancy.

We will review the screening results with you. The screening results may show you are not eligible to join the study, even if you want to.

7. If we find that you have a health problem during screening or during the study, we will tell you about the care that we can give here for free.

For the care that we cannot give, we will explain how we will help you get care elsewhere. For health problems that are unrelated to the study, we will not pay for care.

8. If you were assigned female sex at birth and could become pregnant, you must agree to use birth control to join this study.

You should not become pregnant during the study because we do not know how the study vaccines could affect the developing baby.

You must agree to use effective birth control from 21 days before your first injection until 3 months after your last study injection.

Effective birth control means using any of the following methods every time you have sex:

Birth control drugs that prevent pregnancy—given by 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 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 reached menopause, with no menstrual periods for one year;

You have had a hysterectomy (your uterus removed);

You have had your ovaries removed;

You have a tubal ligation (your "tubes tied") or confirmed successful placement of a product that blocks the fallopian tubes;

You are having sex only with a partner(s) assigned female sex at birth;

You only have oral sex; or,

You are sexually abstinent (no sex at all).

Remember: If you are having sex, male and female condoms are the only birth control methods that also provide protection against HIV and other sexually transmitted infections.

If you join the study, we will test you for pregnancy at some visits, including before each study injection.

Being in the study

If you meet the study requirements and want to join, here is what will happen:

9. **You will come to the clinic for scheduled visits about 11 times over 12 months.**

   Visits can last from approximately 30 minutes to 1 hour.

   You may have to come for more visits if you have a lab or health issue.

   We may contact you after the main study ends (for example, to tell you about the study results).

10. **We will give you $50 for each vaccine visit and $30 for each non-vaccine visit you complete.**

    This amount is to cover the costs of your time and study participation. There are no costs to you for participating in this study. The total amount you may receive if you complete the study is $390.00.

    Payments you receive for being in the study may be taxable. This happens if we pay you more than $600 between January 1 and December 31 of the same calendar year. The clinic staff will need to ask you for your Social Security number for tax reasons.

    You do not have to pay anything to be in this study.

11. **We will give you either the gp120S study vaccine or the gp120T study vaccine.**

    Half the people in this study will get the gp120S study vaccine and half will get the gp120T study vaccine. We will compare the results.

    Whether you get the gp120S or gp120T study vaccine is completely random, like flipping a coin.

    We have no say in whether you get the gp120S or gp120T study vaccine. We will not know which one you are getting, and neither will you. Only the pharmacist at this clinic will have this information while the study is going on.

    You will have to wait until everyone completes their final study visits to find out whether you got the gp120S or gp120T study vaccine. This could be several years. But, if you have a serious medical problem and need to know what you got before the end of the study, we can tell you.

12. We will give you the study products on a schedule.

You will be in one of 2 groups. You will get 3 injections during the study in your upper arm.

	Injection Schedule		
Group	First injection	2 month later	6months later
1	gp120S	gp120S	gp120S
2	gp120T	gp120T	gp120T

You will have to wait in the clinic for about a half hour after each injection to see if there are any problems. Then for that night and for 7 more days, you will need to keep track of how you are feeling and if you have any symptoms. Within 3 days of each injection, we will also ask you how you are doing. Contact the clinic staff if you have any issues or concerns after getting an injection. If you have a problem, we will continue to check on you until it goes away.

13. In addition to giving you the study products, we will:

- Do regular HIV testing, as well as counseling on your results and on how to avoid getting HIV
- Do physical exams
- Do pregnancy tests if you were assigned female sex at birth
- Ask questions about your health, including medications you may be taking
- Ask questions about any personal problems or benefits you may have from being in the study
- Take urine and blood samples.

When we take blood, the amount will depend on the lab tests we need to do. It will be some amount between 10 mL and 275 mL (2 teaspoons to a little over 1 cup). 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 500 mL in an 8-week period.

14. We will counsel you on avoiding HIV infection.

We will ask you personal questions about your HIV risk factors such as sexual behavior, alcohol, and drug use. We will talk with you about ways to keep your risk of getting HIV low.

15. 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 become HIV infected, 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.

16. 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 at the end of this form. If you have any questions, please ask.

Do I have to agree? No. You are free to say yes or no, or to change your mind after you sign this form. At your request, we will destroy all extra samples that we have. Your decision will not affect your being in this study or have any negative consequences here.

Where are the samples stored? 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.

How long will the samples be stored? There is no limit on how long your extra samples will be stored.

Will I be paid for the use of my samples? No. Also, 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 researcher is not likely to ever know who you are.

Will I benefit from allowing my samples to be used in other studies? Probably not. Results from these other studies are not given to you, this clinic, or your doctor. They are not part of your medical record. The studies are only being done for research purposes.

Will the HVTN sell my samples and information? No, but the HVTN may share your samples with HVTN or other researchers. Once we share your samples and information, we may not be able to get them back.

How do other researchers get my samples and information? When a researcher wants to use your samples and 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.

What information is shared with HVTN or other researchers? The 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, sex, health information from the study, and HIV status. We may share information about the study product you received and how your body responded to the study product.

What kind of studies might be done with my extra samples and information? The studies will be related to HIV, vaccines, 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, 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 is very small. There may be other unknown risks.

Who will have access to my information in studies using my extra samples?

People who may see your information are:

Researchers who use your extra samples and information for other research

Government agencies that fund or monitor the research using your extra samples and information

Any regulatory agency that reviews clinical trials,

The researcher's IRB or EC

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 and information may be published. No publication will use your name or identify you personally.

17. We will do our best to protect your private information.

Your study records and samples will be kept in a secure location. We will label all of your samples and most of your records with a code number, not your name or other personal information. However, it is possible to identify you, if necessary. We will not share your name with the lab that does the tests on your samples, or with anyone else who does not need to know your name.

We do need to share your name with the HVTN in case you need proof in the future that you participated in an HIV vaccine study. The HVTN will keep your name in a secure file with these items:

- The name of your study
- Your age or date of birth
- Your study ID number
- What study product(s) you received

There are no HIV test results kept in this file. The HVTN will not share any information that could identify you without your agreement. The HVTN will remove your name from the file if you do not want it there.

Clinic staff will have access to your study records. Your records may also be reviewed by groups who watch over this study to see that we are protecting your rights, keeping you safe, and following the study plan. These groups include:

- The US National Institutes of Health and its study monitors,
- The US Food and Drug Administration (FDA),
- Any regulatory agency that reviews clinical trials,
- Vanderbilt Institutional Review Board,
- Vanderbilt Environmental Health & Safety
- Infectious Disease Research Institute (IDRI) and people who work for them,
- The HVTN and people who work for them,
- The HVTN Safety Monitoring Board and
- The US Office for Human Research Protections.

All reviewers will take steps to keep your records private.

We cannot guarantee absolute privacy. At this clinic, we have to report the following information: Persons with positive syphilis or hepatitis test results will be reported to the Tennessee Department of Health and be referred for appropriate medical care.

We have a Certificate of Confidentiality from the US government, to help protect your privacy. With the certificate, we do not have to release information about you to someone who is not connected to the study, such as the courts or police. Sometimes we can't use the certificate. Since the US government funds this research, we cannot withhold information from it. Also, you can still release information about yourself and your study participation to others.

The results of this study may be published. No publication will use your name or identify you personally.

We may share information from the study with other researchers. We will not share your name or information that can identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

18. **We may stop your 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 more injections.**

    This may happen if:

    - you do not follow instructions,
    - we think that staying in the study might harm you,
    - you enroll in a different research study where you get another study product, or
    - the study is stopped for any reason.

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

19. **We will stop your injections if you become pregnant.**

    We will encourage you to stay in the study if you choose. We will discuss your study options with you.

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

20. **If you get infected with HIV during the study, we will stop your injections, take fewer samples, and help you get care and support.**

    We will encourage you to stay in the study for up to 6 months if you choose. We will discuss your study options with you. We will counsel you about your HIV infection and about telling your partner(s). We will tell you where you can get support and medical care. We will not provide or pay for any of your HIV care directly.

Other Risks

21. **There are other risks to being in this study.**

    This section describes the other risks and restrictions we know about. There may also be unknown risks, even serious ones. We will tell you if we learn anything new that may affect your willingness to stay in the study.

    Risks of routine medical procedures:

    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. Taking blood can cause a low blood cell count (anemia), making you feel tired.

Personal problems/discrimination/testing HIV antibody positive:

About 10 to 20% of people who join HVTN studies report personal problems or discrimination because of joining an HIV vaccine study. Family or friends may worry, get upset or angry, or assume that you are infected with HIV or at high risk and treat you unfairly as a result. Rarely, a person has lost a job because the study took too much time away from work, or because their employer thought they had HIV.

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 HIV study vaccines. The study vaccines may cause you to test positive on some types of HIV antibody tests, even if you are not infected with HIV. This is called vaccine-induced seropositivity (VISP). VISP means that after you get the study vaccines, 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 vaccines.

If you have a positive test result caused by the study vaccines 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 vaccines. 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.

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 are infected with HIV even if you are 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 vaccines, 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 an HIV infection, 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 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.

Risks of genetic testing:

It is unlikely, but the genetic tests done on your samples 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.

Unknown risks:

We do not know if the study vaccines will increase, decrease, or not change your risk of becoming infected with HIV if exposed. If you get infected with HIV, we do not know how the study [vaccine(s)] might affect your HIV infection or how long it takes to develop AIDS.

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

We do not know how the study vaccines will affect a pregnant participant or a developing baby.

Benefits

22. The study may not benefit you.

We do not expect the study vaccines 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.

This study may help in the search for a vaccine to prevent HIV. However, if the study vaccines later become approved and sold, there are no plans to share any money with you.

Your rights and responsibilities

23. If you join the study, you have rights and responsibilities.

You have many rights that we will respect. You also have responsibilities. We list these in the Participant's Bill of Rights and Responsibilities. We will give you a copy of it.

Leaving the study

24. Tell us if you decide to leave the study.

You are free to leave the study at any time and for any reason. Your care at this clinic and your legal rights will not be affected, but it is important for you to let us know.

We will ask you to come back to the clinic one last time for a physical exam, and we may ask to take some blood and urine samples. We will also ask about any personal problems or benefits you have experienced from being in the study. We believe these steps are important to protecting your health, but it is up to you whether to complete them.

Injuries

25. If you get sick or injured during the study, contact us immediately.

Your health is important to us. We will tell you about the care that we can give here. For the care that we cannot provide, we will explain how we will help you get care elsewhere.

If you become sick or injured in this study, there is a process to decide if it is related to the study products 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 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.

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 it is determined by Vanderbilt and the investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. 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.

Health Contact

26. After your clinic visits end, we will contact you 18 months after your first injection.

We will contact you by phone, email, or text message 18 months after your first injection to ask questions about your health. If you prefer to answer these questions in person, you can come to the clinic to do this.

If we have any concerns about your health, we may need to have more contact with you. You are also welcome to contact us at any time if you have concerns about your health related to being in the study.

If we ask you to come to the clinic, we will give you $30 for each visit.

If someone outside this study clinic told you that you are infected with HIV, we will ask you to come back to the clinic for another HIV test. We will draw about 15 mL (1 tablespoon) of blood. We may ask you to come back more than once for this testing.

Because we will want to contact you after the main study, please tell us if your contact information changes, if you are moving away, or if you do not want us to contact you anymore.

You can tell us at any time that you don't want us to contact you after the main study. If you do so, you will not lose any benefits or rights you would normally have.

All other information that is discussed earlier in this consent also applies to the 18 month health contact.

Principal Investigator: [redacted] MD **Revision Date**: 4.23.19
Study Title: A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1–uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells (HVTN 123, Version 1)
Institution/Hospital: Vanderbilt University Medical Center

Questions

27. **If you have questions or problems at any time during your participation in this study, use the following important contacts.**

If you have questions about this study or symptoms that you think may be related to this study, contact [redacted] MD or [redacted], RN at [redacted].

This study has been reviewed and approved by a committee called the Vanderbilt University Institutional Review Board. If you have questions about your rights as a research participant, or problems or concerns about how you are being treated in this study, contact the Vanderbilt University Institutional Review Board Office at [redacted] or toll free at [redacted].

If you want to leave this study, contact [redacted], RN at [redacted].

Your permissions and signature

28. **In Section 16 of this form, we told you about possible other uses of your extra samples and information, outside this study. Please choose only one of the options below and write your initials or make your mark in the box next to it. Whatever you choose, the HVTN keeps track of your decision about how your samples and information can be used. You can change your mind after signing this form.**

☐ 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

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

OR

☐ 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.

Principal Investigator: [redacted] MD **Revision Date**: 4.23.19
Study Title: A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1–uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells (HVTN 123, Version 1)
Institution/Hospital: Vanderbilt University Medical Center

28. If you agree to join this study, you will need to sign or make your mark below. Before you sign or make your mark on this consent form, make sure of the following:

- You have read this consent form, or someone has read it to you.
- You feel that you understand what the study is about and what will happen to you if you join.
- You understand what the possible risks and benefits are.
- You have had your questions answered and know that you can ask more.
- You agree to join this study.

You will not be giving up any of your rights by signing this consent form.

Participant's name (print)	Participant's signature or mark	Date	Time

Clinic staff conducting consent discussion (print)	Clinic staff signature	Date	Time

For participants who are unable to read or write, a witness should complete the signature block below:

Witness's name (print)*	Witness's signature	Date	Time

*Witness is impartial and was present for the entire discussion of this consent form.

Principal Investigator: [redacted] MD **Revision Date**: 4.23.19
Study Title: A phase 1 double-blind, randomized, controlled clinical trial in healthy, HIV-1–uninfected adult participants to compare the safety, tolerability and immunogenicity of CH505TF gp120 produced from stably transfected cells to CH505TF gp120 produced from transiently transfected cells (HVTN 123, Version 1)
Institution/Hospital: Vanderbilt University Medical Center

Table of procedures

Procedure	Screening visit	First injection visit	Time after first injection visit							
			2 weeks	2 months	2 months + 2 weeks	6 months	6 months + 2 weeks	9 months	12 months	18 months[2]
Injection		√		√		√				
Medical history	√									
Complete physical	√								√	
Brief physical		√	√	√	√	√	√	√		
Urine test	√		√				√			
Blood drawn	√	√	√		√	√	√	√	√	
Pregnancy test (participants assigned female sex at birth)[1]	√	√		√		√		√		
HIV testing and pretest counseling	√				√	√		√	√	
Risk reduction counseling	√	√	√	√	√	√	√	√	√	
Interview/ questionnaire	√	√	√	√	√	√	√	√	√	
Health contact										√

Not shown in this table is a time after all study participants have completed their last scheduled visit when you can find out what products you received.

[1]Persons who had a total hysterectomy (removal of the uterus verified by medical records) or removal of both ovaries (verified by medical records), are not required to have a pregnancy test.

[2]Contact at 18 months is to collect health information.