

Informed consent form

Title: A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection among men and transgender persons who have sex with men

Protocol number: HVTN 704/HPTN 085, The AMP Study

Site: [Insert site name]

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. We will offer you a copy 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.

About the study

The HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), and [Insert site name] are doing a study to test the antibody called VRC01 against HIV. HIV is the virus that causes AIDS. Antibodies are one of the natural ways the body fights infection. Researchers can also make antibodies in laboratories and give them to people intravenously (with an IV). We will tell you more about this procedure below. This has been done successfully to prevent or treat some other health problems, such as a virus that causes respiratory infections in infants.

About 2700 people will take part in this study at multiple sites in North America, South America, and Switzerland. The researcher in charge of this study at this clinic is [Insert name of site PI]. The US National Institutes of Health (NIH) is paying for the study.

In addition, a similar study will be done with 1500 women in sub-Saharan Africa.

1. We are doing this study to answer several questions.

- Is the antibody safe to give to people?
- Are people able to take the antibody without becoming too uncomfortable?
- Does the antibody lower people's chances of getting infected with HIV?
- If the antibody does lower people's chances of getting infected with HIV, how much of it is needed to provide protection from HIV?

2. The antibody cannot give you HIV.

It is impossible for the antibody to give you HIV. Also, it cannot cause you to give HIV to someone else. However, we do not know if the antibody will decrease, increase, or not change your chance of becoming infected with HIV if you are exposed to the virus.

3. The antibody is experimental.

The antibody being tested is called VRC-HIVMAB060-00-AB. It is an antibody against the HIV virus. From here on, we will call it VRC01 or the antibody. It is an experimental product. That means we do not know whether the antibody will be safe to use in people, or whether it will work to prevent HIV infection. This antibody is used only in research studies.

VRC01 was developed by the Vaccine Research Center at the US National Institutes of Health (NIH).

In laboratory and animal studies, VRC01 attached to and prevented infection by many strains of HIV viruses from around the world. We do not know if antibodies can prevent HIV infection when they are given to people. This study is designed to help us answer that question. At this time there are no plans to make VRC01 for sale.

Risks of VRC01 antibody:

As of April 2017, VRC01 has been given to people in 12 clinical studies in the United States, Peru, Brazil, Switzerland, and in sub-Saharan Africa. In these studies, more than 1800 adults and 33 infants have gotten VRC01 or placebo (a liquid with no antibody in it).

Many of these studies are still going on and we don't know which people got VRC01 and which got a placebo. In early trials, more than 100 people got VRC01 and it did not make them too uncomfortable or cause serious health problems. After receiving the antibody, most people said that they had mild pain, itching, or redness where the antibody was given to them. Of these people, some said they felt like they had the flu after getting the antibody, but that this feeling lasted a few hours at most.

In a previous study, one person who got a VRC01 injection had a rash. One person had a brief fainting spell several hours after getting a VRC01 infusion. To be safe, no more injections or infusions were given to these people. Some participants had mild body discomfort, muscle pain, or joint pain after getting the VRC01 antibody.

VRC01 may have other side effects that we do not know about yet.

General risks of antibodies:

Antibodies that are different from VRC01 have been given to people for other illnesses. With those antibodies most side effects happen within the first 24 hours. Those antibodies have caused fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, trouble breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heartbeat or chest pain.

Rarely, some antibodies have caused serious reactions. These reactions may be life-threatening. Please tell us if you have ever had any of the following reactions.

- One type of serious reaction, called anaphylaxis, may occur soon after getting an antibody. It includes difficulty breathing possibly leading to low blood oxygen, low blood pressure, hives or rash, and swelling in the mouth and face.

- A second type of serious reaction, called serum sickness, may occur several days to 3 weeks after getting an antibody. It includes hives or a rash, fever, big lymph nodes, muscle and joint pains, chest discomfort and shortness of breath.

Rarely, antibodies licensed for treatment of other diseases have been linked to a blood disorder that interferes with blood clotting, to cancer, to damage to the heart muscle, and to the body's immune system attacking healthy cells.

These rare side effects and reactions have not been seen in other studies with the VRC01 antibody.

When antibodies are given to a person by IV they do not last in the body more than a few months. Any antibody given to you in this study should be gone from your body several months after your last dose.

Joining the study

4. 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 some other kinds of 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. 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.

5. 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)
- Checking your veins to see how easy it might be to start an IV

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 ask you about medications you are taking. We will ask you about behaviors that might put you at risk for getting HIV. If you could become pregnant, we will test you for pregnancy. If you have had your uterus or ovaries removed (a hysterectomy or oophorectomy), verified by medical records, you are not required to have a pregnancy test.

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.

6. 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.

7. If you 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 antibody could affect the developing baby. You must agree to use effective birth control from 21 days before you first receive the antibody until your last scheduled clinic visit (about 1¾ years after your first IV). We will talk to you about effective birth control methods. They are listed on a handout that we will give to you.

Being in the study

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

8. You will come to the clinic for scheduled visits about 26 times over about 2 years.

The study will require about 26 visits. You may have to come for more visits if you have a lab or health issue.

Visits can last from about 30 minutes to 2 hours. The IV procedure can take about 15 minutes to an hour.

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

9. We will give you [Site: Insert compensation] for each study visit you complete.

This amount is to cover the costs of your time and travel to the clinic.

Following paragraph for US sites only:

Payments you receive for being in the study may be taxable. We may need to ask you for your Social Security number for tax reasons.

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

10. We will give you either the antibody or a placebo.

Not everyone in this study will get the VRC01 antibody. Some people will get a placebo, a liquid that does not contain any antibody. We will compare the results from people who got the placebo with results from people who got the VRC01 antibody. In this study, the placebo is sterile salt water, which is found naturally in the body.

There are three groups in this study. One group will get a lower dose of the VRC01 antibody, one group will get a higher dose, and one group will get the placebo. The high and low doses of the antibody will be adjusted for your body weight. We will weigh you to determine the amount you will get.

Overall, if you join this study, you have a 2-in-3 chance of getting the study antibody. Whether you get the low dose of the antibody, the high dose of the antibody, or the placebo is completely random, like flipping a coin.

We have no say in whether you get the antibody or the placebo. If you get the antibody, we have no say in which dose you get. We will not know what 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 antibody or the placebo. This could be up to about 5 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.

If it is found to be effective, there are no plans to give the antibody to participants after the study. Instead, we will use what is learned in this study to determine if the antibody would be useful to prevent HIV, how the antibody could be improved, and how to produce it for wide public use.

11. We will give you the antibody or placebo on a schedule.

You will get the VRC01 antibody or the placebo during the study by IV. To get an IV, a needle is used to place a small plastic tube into a vein in your arm. The tube is connected to a small bag of fluid that contains the antibody or placebo. An IV pump controls how fast the fluid drips from the bag, through the tube, and into your vein. There will be 10 IV procedures, one IV every 8 weeks. Other study visits will not include IVs.

Infusion schedule											
		6 months 1 year →									
Group	Dose	First IV	Weeks after first IV								
			Wk 8	Wk 16	Wk 24	Wk 32	Wk 40	Wk 48	Wk 56	Wk 64	Wk 72
Group 1	Lower dose VRC01	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group 2	Higher dose VRC01	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Group 3	Placebo	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

You will have to wait in the clinic for about 30 minutes after the first IV to see if there are any problems. You probably will not have to wait after the IVs at the rest of the IV visits. After each IV visit, for that night and for three more days, you will be asked to keep track of how you feel. To help you do this, we can give you tools and show you how to use them. We will ask you the ways we can contact you. We will contact you about 3 days after each IV visit to ask how you have been feeling. Contact the clinic staff if you have any concerns after getting an infusion. If you have a problem, we will continue to check on you until it goes away

12. In addition to giving you the antibody or placebo, 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 could become pregnant;
- 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; and
- 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 30 mL and 180 mL (6 teaspoons to $\frac{3}{4}$ cup). Your body will make new blood to replace the blood we take out.

	6 months 1 year 1½ years																									
Procedure	Screening visit(s)	First IV	4 weeks	8 weeks	8 weeks + 5 days	12 weeks	16 weeks	20 weeks	24 weeks	28 weeks	32 weeks	36 weeks	40 weeks	44 weeks	48 weeks	52 weeks	56 weeks	60 weeks	64 weeks	68 weeks	72 weeks	76 weeks	80 weeks	84 weeks	88 weeks	92 weeks
IV		✓		✓			✓		✓		✓		✓		✓		✓		✓		✓					
Medical history	✓																									
Complete physical exam	✓																									✓
Brief physical exam		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓						
Urine test	✓		✓																							✓
Blood drawn	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pregnancy test*	✓	✓		✓			✓		✓		✓		✓		✓		✓		✓		✓		✓			
HIV test & pretest counseling	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk reduction counseling	✓	✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
Interview/Questionnaire	✓	✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
STI testing (blood, urine, and/or swabs) †		✓							✓						✓						✓					

We will be looking for side effects.

We will do blood tests for syphilis and urine tests for gonorrhea and chlamydia. We will also test for gonorrhea and chlamydia using rectal swabs. We will do these tests at 4 visits. We will also test for gonorrhea and chlamydia using mouth and throat swabs at your first infusion visit. We will explain what each of these infections is. If the tests show that you have an infection, we will provide counseling and will help you get treatment. This study cannot pay for that treatment.

We will review the results of the procedures and tests with you at your next visit, or sooner if necessary. If any of the results are important to your health, we will tell you.

13. We will test your samples for this study.

We will send your samples (without your name) to labs approved by the HVTN and the HPTN for this study. These labs are located in the United States, South America, and South Africa. The samples will be tested to:

- measure how much antibody is in your blood,
- see how your immune system responds to the antibody, and
- see if there is antiretroviral medicine (also called ART/ARV) in your blood.

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. These types of genetic tests involve only some of your genes, not all of your genes (your genome). The researchers will study 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 antibody.

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.

Tests done on your samples are for research purposes only. The labs will not give the results to you or this clinic, and the results will not become part of your study record.

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

14. When samples are no longer needed for this study, the study sponsors want to keep them for use in other studies by HVTN, HPTN, or other researchers. We will call these "extra samples."

This section gives you information so you can decide if you want your extra samples and information used in other studies. You will mark your decision at the end of the 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 needed for your medical care. They are not part of your medical record. The studies are only being done for research purposes.

Will the HVTN or HPTN sell my samples and information? No, but the HVTN and HPTN may share your samples with other researchers. Once we share your samples and information, we will 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/or information, their research plan must be approved by the HVTN and HPTN. 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 and HPTN will send your samples to the researcher's location.

What information is shared with other researchers? The samples and limited 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 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 prevention or infection, the immune system, and other diseases.

Researchers may also do genetic testing on your samples.

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.

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. 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.

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

People who may see your information are:

- Researchers who use your stored samples and limited information for other research
- Government agencies that fund or monitor the research using your samples or information
- Any regulatory agency that reviews clinical trials
- The researcher's Institutional Review Board or Ethics Committee
- 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.

15. We will counsel you on reducing your risk for HIV infection.

We will ask you personal questions about your HIV risk factors such as sexual behavior and drug use. We will provide you with condoms and lubricant. We will talk with you about ways of lowering your risk of getting HIV. We will help you develop a risk reduction plan. Some topics we may discuss include:

- What you think causes risky behavior for you, and
- Ways to avoid getting HIV or giving it to someone else

These methods may include not having sex, using condoms, or other behavior changes. We will talk about new methods of HIV prevention, including pre-exposure prophylaxis (PrEP) with a drug called Truvada, and help you decide which of these methods is right for you.

[Site: The text in the next two paragraphs applies to US sites only. Sites should adjust the language in this paragraph to match local PrEP availability.] Gilead Sciences, Inc. (the maker of Truvada) has agreed to provide Truvada as PrEP to study participants in HVTN 704/HPTN 085 through a mail order pharmacy. If you are interested, we can give you more information about this program. We can refer you to health care providers who can prescribe PrEP either through the Gilead program or from a different source.

If you accept the Gilead Sciences, Inc. offer to receive Truvada as PrEP during the study, the following study data will be shared with Gilead Sciences, Inc.:

- Your study ID code number
- Information such as your age, sex at birth, and gender
- Your past and present health conditions

Truvada has been shown to substantially lower people's risk of getting HIV when taken every day. The US FDA has approved it for use as PrEP in adults at risk of HIV infection through

sexual contact. There are several considerations to talk about with your health care provider to see if PrEP is the right choice for you. If you decide to take Truvada PrEP, your health care provider will prescribe it for you and monitor your health while you use it.

[Site: The text in the next two paragraphs applies to South American sites only. Sites should adjust the language in this paragraph to match local PrEP availability.] Gilead Sciences, Inc. (the maker of Truvada) has agreed to provide Truvada as PrEP to study participants in HVTN 704/HPTN 085 through a local project. If you are interested, clinic staff can give you more information about this project and can refer you to it for PrEP.

PrEP has been shown to lower people's risk of getting HIV when taken once every day. There are several medical considerations to talk about with health care providers at the project to see if PrEP is the right choice for you. A provider at the project will prescribe PrEP for you and monitor your health while you use it.

In this study, we will look at how many participants use PrEP. We will also try to find out if using PrEP has any effect on how VRC01 works.

16. If you are HIV infected when you enroll or become infected during the study, we will help you get care and support.

We will test your blood for HIV before your first IV and during the study. Each time, it will take a few days to complete the tests. If you are infected with HIV, you cannot stay in the study for its whole length. If that happens, we will tell you as soon as possible. We will also ask you to come to the clinic for 3-6 more visits. We will tell you more about what will happen at these visits in another form.

17. If you are found to have HIV-1 when you enroll, or if you have HIV-2:

If you are found to have HIV when you enrolled, you already had HIV before you got the antibody or placebo. It takes a few days to complete the tests to see if you have HIV, so your diagnosis was not made until after you got your first IV.

HIV-2 is a rare kind of HIV, most often found in West Africa. In North and South America, there are only about a dozen cases reported each year.

We will counsel you about your HIV, talk with you about ways to avoid transmission and about telling your partner(s).

We are asking you to come to the clinic for 1-2 more visits (including today) within about 6 months of your diagnosis. At these visits, we will:

- Ask questions about your health;
- Do physical exams based on your complaints or side effects;
- Ask questions about your sexual behavior and drug use;
- Counsel you on how to avoid transmitting HIV to other people;

- Collect blood samples (between 30 and 45 mL, or about 2 to 3 tablespoons, at each visit); and
- Ask questions about any personal problems or benefits you may have from participating in the study.

Procedure	Weeks after 1 st positive HIV test	
	4	24
Medical history (as needed)	√	√
Brief physical (as needed)	√	√
Complete physical		√
Risk reduction counseling	√	√
Questions/questionnaire	√	√
Blood drawn	√	√

18. If you get HIV-1 during the study:

If you became infected with HIV-1, we will counsel you about your HIV infection, talk with you about ways to avoid transmission and about telling your partner(s). You will not get any more IVs. We will ask you to come in for 4-5 more visits within about 6 months of your diagnosis. At these visits, we will:

- Ask questions about your health;
- Do physical exams based on your complaints or side effects;
- Ask questions about your risk of infecting others with HIV, including sexual behavior and drug use;
- Counsel you on ways to avoid transmitting HIV to other people;
- Collect blood samples (between 70 mL and 130 mL, about $\frac{1}{3}$ to $\frac{1}{2}$ cup, at each visit); and
- Ask questions about any personal problems or benefits you may have from participating in the study.

Procedure	Weeks after 1st positive HIV test				
	4	6	8	12	24
Medical history (as needed)	√	√	√	√	√
Brief physical (as needed)	√	√	√	√	
Complete physical					√
Risk reduction counseling	√	√	√	√	√
Questions/questionnaire	√	√	√	√	√
Blood drawn	√	√	√	√	√
Pregnancy test*				√	

19. If you stop getting IVs for reasons other than an HIV diagnosis, we may encourage you to stay in the study.

In this case, we will ask you to come in for study visits about every 3-4 months until 104 weeks (2 years) after your first infusion. That is how long you would be in the study if you got all the infusions on schedule. Because you got some IVs, we want to keep track of your health. How many visits you will have will depend on when you stopped getting IVs. At these visits we will:

- Ask questions about your health, including medications you may be taking;
- Do physical exams based on your complaints or side effects;
- Do regular HIV testing, as well as counseling on your results and on how to avoid getting HIV;
- Ask questions about any personal problems or benefits you may have from participating in the study;
- Do pregnancy tests if you could become pregnant; and
- Collect blood samples (between 70 mL and 120 mL, about $\frac{1}{3}$ to $\frac{1}{2}$ cup, at each visit).

Procedure	Weeks after enrollment							
	8	20	32	44	56	68	80	92
Brief physical (as needed)	√	√	√	√	√	√	√	
Complete physical								√
HIV testing & pretest counseling	√	√	√	√	√	√	√	√
Risk reduction counseling	√	√	√	√	√	√	√	√
Questions/questionnaire	√	√	√	√	√	√	√	√
Pregnancy test*	√	√	√	√	√	√	√	√
Blood drawn	√	√	√	√	√	√	√	√

20. We may stop your IVs and 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 IVs.

This may happen if:

- we learn that you were enrolled in the study in error,
- you are unable to 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 take you out of the study, 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 person problems or benefits you have experienced from being in the study.

21. We will stop your IVs if you become pregnant during the study.

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.

22. 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.

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, people who work for them, its study monitors, and its chosen South African representatives,
- The US Food and Drug Administration,
- Any regulatory agency that reviews clinical trials
- [Insert name of local IRB/EC] ,
- [Insert name of local and/or national regulatory authority as appropriate],
- The HVTN and HPTN and people who work for them,

- The US National Institutes for Allergy and Infectious Diseases Data and 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:

Site: Include any public health or legal reporting requirements. Bulleted examples should include all appropriate cases (reportable communicable disease, risk of harm to self or others, etc.).

- [Item 1]
- [Item 2]
- [Item 3]

US sites only include this paragraph: 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>, as required by U.S. Law. 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.

Other Risks

23. 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 taking blood:

Taking blood can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, and (rarely) muscle damage or infection where the needle was inserted. Taking blood can cause a low blood cell count (anemia), making you feel tired.

Risks of the IV procedures:

Getting an IV may cause stinging, discomfort, pain, soreness, redness, bruising, itching, rash, and swelling where the needle goes into the skin. Rarely, needle sticks can result in infections.

Personal problems/discrimination:

Some people who join HVTN or HPTN studies report personal problems or discrimination because of joining an HIV prevention 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.

HIV testing

HIV antibody tests are the usual way to test for HIV infections. Although 2 out of 3 people in this study will get an HIV antibody, we do not expect them to test positive on HIV antibody tests. We have used several common HIV antibody tests to test samples of blood containing the VRC01 antibody and none of them detected the antibody.

Although it has not been seen so far, getting VRC01 may cause common HIV antibody tests to show that someone is HIV-negative, even if they are actually infected.

To be absolutely safe we ask you to get HIV tests only at this clinic during the study. Our tests can always detect true HIV infection. They can also tell if someone is really not HIV infected. Since the antibodies do not last long in the body, we do not expect you to have any problems with HIV testing after the study ends.

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:

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.

U.S. Sites, include the following paragraph 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 antibody will increase, decrease, or not change your risk of becoming infected with HIV if exposed.

If we find that you were already HIV infected when you got the antibody, we do not know how the antibody will affect your HIV disease. We also do not know how having gotten it will affect your HIV-related lab results.

If you get infected with HIV during the study, we do not know how the antibody might affect the course of your HIV disease.

If you become pregnant while you still have VRC01 in your body, we don't know if it could be passed to your baby. We do not know how the antibody will affect a pregnant participant or a developing baby.

Benefits

24. The study may not benefit you.

Since we do not know if the antibody can prevent HIV infection in people, you should not expect any benefit from getting the antibody in this study. 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 show us that the VRC01 antibody can prevent HIV and the study results may also help in the search for methods to prevent HIV. However, if the VRC01 antibody later becomes approved and sold or leads to an HIV prevention method, there are no plans to share any money with you.

Your rights and responsibilities

25. 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

26. 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.

If you decide to leave the study, 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

27. 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 VRC01 antibody and/or study procedures. If it is, we call it a study-related injury.

The HVTN and HPTN have limited funds to pay medical costs for study-related injuries that it determines are reasonable. *(Sites: insert locale-appropriate medical insurance language in the following sentence)* 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 prevention 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, independent experts will be asked to review the decision. You always have the right to use the court system if you are not satisfied.

Questions

28. 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, contact [name and telephone number of the investigator or other study staff].

If you have any symptoms that you think may be related to this study, contact [name and telephone number of the investigator or other study staff].

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 [name/title/phone of person on IRB or other appropriate organization].

If you want to leave this study, contact [name and telephone number of the investigator or other study staff].

Your permissions and signature

29. In Section 14 of this form, we told you about possible other uses of your extra samples and limited 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 and HPTN keep track of your decision about how your samples and information can be used.

☐

I allow my extra samples combined with limited information to be used for other studies related to HIV prevention, 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 combined with limited 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.

30. 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 consent process.			