Appendix A Sample informed consent form

A phase 1 clinical trial to evaluate the safety and pharmacokinetics of VRC-HIVMAB075-00-AB (VRC07-523LS) in the sera and mucosae of healthy, HIV-1–uninfected adult participants

Protocol number: HVTN 128

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) and [Insert site name] are doing a study to test an antibody against HIV called VRC07-523LS. HIV is the virus that causes AIDS. Antibodies are one of the ways the human body fights infection. Antibodies are natural proteins that the body can make to prevent infectious agents such as bacteria and viruses from making you sick. Researchers can also make antibodies in laboratories and give them to people intravenously (with an IV). We will tell you more about these procedures below. Antibodies have been used successfully to prevent or treat some other health problems, such as a virus that causes respiratory infections in infants.

About 24 people will take part in this study at multiple sites. 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.

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

   - Is the study VRC07-523LS antibody safe to give to people?
   - Are people able to take the study antibody without becoming too uncomfortable?
   - How much of the antibody remains in the body as time passes?
   - How much of the antibody is found at the rectum, vagina, and penis?
   - How does the body's response to the antibody change depending on the amount and timing of the doses?

2. The antibody cannot give you HIV.

The study antibody is not made from actual HIV. It is impossible for the antibody to give you HIV. Also, it cannot cause you to give HIV to someone else. 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. This study antibody is experimental.

The formal name of the study antibody is VRC-HIVMAB075-00-AB. From here on, we will call it VRC07-523LS or the study antibody.

VRC07-523LS is an experimental product. That means we do not know if it will be safe to use in people, or if it will work to prevent HIV infection. VRC07-523LS is used only in research studies.

VRC07-523LS was developed by Vaccine Research Center at the US National Institutes of Health (NIH).

In laboratory and animal studies, the study antibody attached to and prevented infection by many kinds of HIV viruses from around the world. We do not know if it will act the same way when given to people. It will take many studies to learn if it will be useful for prevention of HIV or treatment of HIV. This study alone will not answer these questions.

Risks of the VRC07-523LS antibody:

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 VRC07-523LS antibody has been tested for safety in animals. In animal studies, no safety problems were seen at doses 13 times higher than those used in this study.

As of July 2018, VRC07-523LS has been given by injection or by intravenous infusion (IV) in ongoing clinical trials at the NIH Clinical Center and in a multisite study. In the VRC 605 study, 25 participants have received the antibody by injection or by intravenous infusion (IV). In the HVTN 127/ HPTN 087 clinical trial, VRC07-523LS has been given by IV infusion to 24 people (8 people have received a low dose, 8 people have received a medium dose, and 8 people have received a high dose of the antibody). So far, the study antibody has not made people too uncomfortable or caused serious health problems. Two people who got the study antibody by infusion had chills, fever, nausea, body aches, rapid heartbeat, and headache. These feelings went away within 12 hours.

General risks of antibodies similar to VRC01:

As of July 2018, similar antibodies called VRC01 and VRC01LS have been given to people in 14 clinical studies in the United States, Peru, Brazil, Switzerland, Thailand, and in sub-Saharan Africa. In these studies, more than 3000 adults and 60 infants have gotten those study products.

In a previous study, one person who got VRC01 by injection had a rash. One person had a brief fainting spell several hours after getting VRC01 by IV 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 a study antibody.

Many of these studies are still going on and we don’t know which people got the study antibodies and which people got a placebo (a liquid with no antibody in it). After receiving the antibody or a placebo, many people said that they had mild pain, itching, or redness where the antibody or placebo 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.

VRC07-523LS and VRC01 may have other side effects that we do not know about yet.

General risks of antibodies:

Antibodies that are different from VRC07-523LS 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, stuffy nose, redness in the face, feeling weak or having low energy, chills, shaking, nausea, vomiting, pain, headache, dizziness, trouble breathing, high or low blood pressure, itchiness, rash, hives, diarrhea, racing heartbeat, chest pain, or swelling in the lip, tongue, throat or face.

Rarely, some antibodies have caused serious reactions that may be life-threatening. Two such serious reactions are:

- Anaphylaxis – a physical reaction that includes difficulty breathing, possibly leading to low blood oxygen, low blood pressure, hives or rash, and swelling in the mouth and face. This may occur soon after getting an antibody.

- Serum Sickness – a physical reaction that includes developing hives or a rash, fever, big lymph nodes, muscle and joint pains, chest discomfort and shortness of breath. This may occur several days to 3 weeks after getting an antibody.

Please tell us if you have ever experienced reactions similar to anaphylaxis or serum sickness, and the cause of the reactions if you remember.

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 VRC07-523LS or similar experimental antibodies.

Antibodies given to a person usually do not last in the body more than a few months. One of the goals of this study is to see how long VRC07-523LS will stay in the body. We don't know yet how long it will last, but it may be several months.

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.

Site: Remove item 5 if you use a separate screening consent that covers these procedures.

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 assess how easy it might be to start an IV
- Rectal and/or pelvic exam

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 syphilis, chlamydia, gonorrhea, Trichomonas vaginalis, bacterial vaginosis, hepatitis B, and hepatitis C. 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. If you were assigned female sex at birth and are 21 years or older, you must have had a Pap smear within the last 3 to 5 years with the most recent result being normal. We will need to request a copy of your Pap smear result. If you have not had a Pap smear within the last 3 years and would like to get one, we will tell you where you can get one.

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.

Site: adapt the following section so it is applicable to the care available at your site

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

Site: If you want to include Appendix B, Approved birth control methods (for sample informed consent form), in this consent form, paste it below and delete paragraph below.

You should not become pregnant during the study because we do not know how the study antibody could affect the developing baby. You must agree to use effective birth control at least 21 days prior to enrollment through the last required protocol clinic visit. 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 about 9 scheduled visits for just under one year.**

We will ask you to come to the clinic about 14 days before the first infusion for tissue collections that will be compared with tissue collections taken after infusions. This is to see how much study product gets into the tissues. You’ll come again within about 2 weeks after each infusion to draw your blood. We will do this so that we can look at how your body responds to the study product.

Visits can last from [#] to [#] hours.

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).

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

This amount is to cover the costs of [Site: Insert text]

Site: Insert any costs to participants (eg, birth control costs for participants assigned female sex at birth who could become pregnant).

US sites: Include the following paragraph:

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 the study antibody by IV infusion.**

There are 2 groups in this study. All people in both groups will get the study antibody by IV. The amount of antibody is different in each of the 2 groups.

When getting an IV, a sterile 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. An IV pump controls how fast the fluid drips from the bag, through the tube, and into your vein. The first IV will take about one hour. Other IVs will probably take about 15 to 60 minutes each.

Which group you are in is completely random, like flipping a coin. We have no say in which group you are assigned to. Neither will you. We can tell you which group you are assigned to.

11. **We will give you the study products on a schedule.**

You will be in one of 2 groups. Both groups will get an IV infusion 3 times during the study, about every 4 months. You will get a different dose depending on which group you are in.

Participants in Group 1 will get the lower dose. Participants in Group 2 will get the higher dose.

Group	Route	Dose	IV schedule		
			First infusion	4 months later	8 months later
1	IV	Lower	X	X	X
2	IV	Higher	X	X	X

You will have to wait in the clinic for about an hour after the first IV infusion and for about half an hour after the other IVs to see if there are any problems. Then for that night and for 3 more days, you will need to keep track of how you are feeling and if you have any symptoms. We will ask you the ways we can contact you. We will contact you about 3 days after each infusion to ask how you have been feeling. Contact the clinic staff if you have any issues or 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 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 17 mL and 100 mL (2 tablespoons to 1/2 cup). Your body will make new blood to replace the blood we take out.

Site: You may want to add a sentence to the end of the previous paragraph contextualizing the blood volumes described (eg, "To compare, people who donate blood in the US can give a total of about 500 mL in an 8-week period."). Modify the example for cultural relevance and alter blood volumes as necessary.

Site: Insert Appendix D, Table of procedures (for informed consent form) in this section or distribute it as a separate sheet if it is helpful to your study participants. You are not required to do either.

We will be looking for side effects. We will review the results of these 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 also collect semen, rectal fluid and tissue, cervical fluid and cervical and vaginal tissue samples from you.

We want to see if the antibodies get to the parts of the body where people may be exposed to HIV: their rectum, vagina, and penis. We will take samples from these areas.

We will ask you to avoid some activities before we collect these samples. This will help make sure your samples give accurate lab readings. There are also some activities we will ask you to avoid after collecting the samples that are described below.

We will ask all participants assigned male sex at birth to provide semen as well as rectal fluids and tissue. We will ask all participants assigned female sex at birth to provide cervical and rectal fluids as well as cervical, rectal and vaginal tissues.

Site: localize measurement units throughout the following sections as needed.

Semen collections (for persons assigned male sex at birth)

You will provide semen at the clinic. We will ask you to ejaculate into a plastic cup, which we will give to you.

For the **2 days before** semen collection, we will ask you to follow these instructions:

- Do not ejaculate, or have oral, vaginal, or anal insertive sex,
- Do not use anything with lubricants,
- Do not put saliva (your own or someone else's) on your penis.

Rectal fluid collections (for all participants)

We will collect rectal fluid by first placing a plastic tube about 2 cm wide (a little less than an inch) into your rectum to hold it open. The tube will go in about 6½ cm (about 2½ inches). A small balloon will be placed through the tube and into the rectum. The balloon will stay in for less than a minute. The balloon will be inflated to about half the size of a chicken egg after it is inside your rectum, and deflated before it is removed.

For the **2 days before** we collect your rectal fluid, we will ask you to follow these instructions:

- Do not have receptive anal intercourse,
- Do not put anything into your anus, including cleaning products (creams, gels, lotions, pads, etc.), lubricant, enemas or douches (even with water),
- Do not use any anti-inflammatory creams in or around your anus,
- We will not collect rectal fluid if we think you may have an anal or rectal infection. You should tell us if your rectal area is sore.

Rectal tissue collections (for all participants)

We will collect small samples of tissue about the size of half a grain of rice from the lining of your rectum. These are called rectal biopsies. We will collect 2 biopsies at 4 different visits. To take the samples, we will place a plastic tube about 2 cm wide (a little less than an inch) into the anus to view the lower part of the rectum. You may feel some discomfort, but the biopsies are almost always painless. It will take 5 to 10 minutes.

You may see blood in your first few stools. This is normal after a biopsy. If you think the bleeding is excessive, contact your study clinician immediately.

For the 5 days before we collect your rectal tissues, we will ask you not to take medicines that thin your blood or prevent blood clots. These medicines are called NSAIDS, and common examples include Ibuprofen (brand name Advil®) and Naprosyn (brand name Aleve®).

For the 2 days before we collect your rectal tissues, we will ask you to follow the same instructions as above. In addition, we will ask you to follow these instructions after the procedure:

- Do not have rectal sex and/or insert any foreign object or substance into the rectum for 5 days after biopsy samples have been collected;
- You should call the clinic if you have a lot of bleeding, have a temperature of more than 38.1°C (100.5°F), experience chills, or have pain that is not getting better.

Cervical fluid collections (for persons assigned female sex at birth)

We will collect cervical fluids by using either a soft sponge inserted into the opening of your cervix, or by using a disposable menstrual cup inserted into your vagina. If we use a soft sponge to collect cervical fluids, we will insert a speculum (a device that holds your vagina open) into your vagina and place the sponge in the opening of the cervix. This is similar to getting a pap smear. If we use a menstrual cup, we will explain how to insert it into your vagina. You may insert it before you come to the clinic. You will wear it for up to 6 hours and remove it at the clinic. You will insert a second menstrual cup at the clinic and wear it for 10-

15 minutes. If you are uncomfortable doing any of this on your own, you may come to the clinic and we will help you.

For the 2 days before we collect your cervical fluid, we will ask you to follow these instructions:

- Do not use any spermicide, lubricants, douche (even with water), or medication in or around your vagina;
- Do not have vaginal intercourse or insert anything into your vagina;
- Using a vaginal ring for contraception is fine and can continue to be used. You will need to remove it for a few hours before the procedure. The clinic staff can explain this to you.

We will not collect cervical fluid if you are menstruating, or if we think you may have a cervical or vaginal infection. If you are menstruating, we may ask you to return to collect this sample at another time.

Cervical and vaginal tissue collections (for persons assigned female sex at birth)

We will collect small samples of tissue about the size of half a grain of rice. We will collect up to 2 cervical and 2 vaginal biopsies at 4 different visits. We will insert a speculum into your vagina. A speculum is a metal or plastic tool that looks like a bird's beak. It is used to help open your vagina a few inches.

After the speculum is put into your vagina, the cervix and vaginal wall will be cleaned with a clean cotton ball or swab.

Biopsies will be taken with clean forceps. Forceps are a metal tool to help get the tissue from inside your vagina and cervix. You may feel cramping, pain or discomfort. We will check to make sure that there is no bleeding from where the biopsies are taken. If there is bleeding, we will use a medication to stop it. One type of medication, silver nitrate, has a gray color. You may see gray flecks in your vaginal discharge after the biopsy. This is normal. The procedure will take about 10 minutes.

For the 5 days before we collect your cervical and vaginal tissues, we will ask you not to take medicines that thin your blood or prevent blood clots. These medicines are called NSAIDS, and common examples include Ibuprofen (brand name Advil®) and Naprosyn (brand name Aleve®).

For the 2 days before we collect your cervical/vaginal tissue, we will ask you to follow the same instructions as above. In addition, we will ask you to follow these instructions after the procedure:

- Do not have vaginal sex and/or insert any foreign object or substance, including tampons, into the vagina for 7 days after biopsy samples have been collected;

- Participants should contact the clinic if they experience a large amount of bleeding, have a temperature of more than 38.1°C (100.5°F), experience chills, or have pain that is not improving.

- Using a vaginal ring for contraception is fine and can continue to be used.

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. We will test your samples to see how your immune system responds to the study antibody.

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.

Site: Delete next section if using separate consent for use of samples and information in other studies

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.

These samples are called "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. *[Site: Revise the previous sentence to insert limits if your regulatory authority imposes them.]*

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 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. *[Site: If review by your institution's IRB/EC/RE is also required, insert a sentence stating this.]* 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 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 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 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 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.

Site: Check HIPAA authorization for conflicts with this section.

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 and its study monitors,
- 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 NIH Vaccine Research Center 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:

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]

Site: Include the following boxed text. You can remove the box.

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.

Site: The text below may not be deleted or changed, per FDA requirement. It's OK to remove the box around it.

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 IV infusions 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 IV infusions.

This may happen if:

- you do not follow instructions,
- we think that staying in the study might harm you,
- you get HIV,
- 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 infusions, we may ask you to stay in the study to complete other study procedures.

19. We will stop your IV infusions and most sample collections 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 infusions and most sample collections, and we will help you get care and support.

We will encourage you to stay in the study for up to 16 weeks 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. *Site: Modify the following sentence as appropriate.* 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 giving blood:

In this study, we will do some routine medical procedures. These are taking blood from you. These procedures can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, blood clot, 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 IV infusion 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 a blood clot or infection.

Risks of taking rectal and genital fluids and tissues:

We will ask you to stop some activities before and after we collect these samples. You may find this inconvenient. These sample collections may cause some anxiety, temporary discomfort, and embarrassment. We will try to make you as comfortable as possible.

All biopsies may cause a small amount of bleeding, which usually stops on its own. In rare cases, excess bleeding or infection may occur from a biopsy. If you need care, we will tell you about the care we can give you here. We will also tell you about care we can help you get elsewhere.

Until the areas where the biopsies were taken heal, you may be at increased risk for HIV or other sexually transmitted infection (STI) infection if you are exposed. Most people heal within 5 to 14 days, but some may take longer.

Personal problems/discrimination/testing HIV antibody positive:

Some people who join HVTN 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. We have used several common HIV antibody tests to test samples of blood containing different amounts of the study antibody. Very high VRC07-523LS levels in the blood can cause positive or uncertain results on a few brands of HIV tests. Such high levels might exist for a short time after a person gets the study antibody. This means that for a few days after getting the antibody, certain HIV tests might say a person is infected with HIV when they really aren't.

For this reason, 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.

Although it has not been seen so far, getting VRC07-523LS may cause common HIV antibody tests to show that someone is HIV-negative, even if they are actually infected.

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 antibody 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 antibody might affect your HIV infection or how long it takes to develop AIDS.

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

Benefits

22. The study may not benefit you.

We do not know whether getting the study antibody might 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 antibody or a vaccine later becomes 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

Sites: Approval from HVTN Regulatory Affairs (at vtn.core.reg@hvtn.org) is needed for any change (other than those that the instructions specifically request or those previously approved by HVTN Regulatory Affairs) to the boxed text

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

Your health is important to us. *(Sites: adjust the following 2 sentences if applicable to the care available at your site)* 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 antibody 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 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

26. 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 or title 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 or title and telephone number of the investigator or other study staff].

This study has been reviewed and approved by a committee called the [name of local IRB/EC]. 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 or title and telephone number of person on IRB/EC] , at the committee.

Your permissions and signature

Site: Delete this section if using a separate consent for use of samples and information in other studies

27. 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 keep 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, 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 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.

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.