Columbia University Medical Center
Informed Consent Form – Groups 1-3

Title: A phase 1 clinical trial to evaluate the safety, tolerability, pharmacokinetics, and antiviral activity of combinations of monoclonal antibodies PGT121, PGDM1400, 10-1074, and VRC07-523LS administered via intravenous infusion in healthy, HIV-uninfected adult participants

Protocol number: HVTN 130/HPTN 089

Local IRB number: AAAS4038

Site: Columbia University Medical Center

Anticipated number of subjects: 27

Target number accrual at CUMC: 10

CONTACT:

Contact	Title	Contact Type	Numbers
[redacted]	Medical Doctor Infectious Diseases	Principal Investigator	Telephone: [redacted]
[redacted]	Site Coordinator	Study Coordinator	Telephone: [redacted]

Key Information

Your participation in this research study is voluntary. It is your choice whether or not you take part in this study. If you choose to participate in this study, we will ask for your consent.

The purpose of this study is to test combinations of different antibodies against HIV. This study will look to see if antibodies are safe to give to people in combination, can be given without being too uncomfortable, how much of the antibodies remain over time and how does the body's response change depending on the combination given.

There are a total of 4 groups in this study. You are being invited to join Group 1, 2, or 3 of the study. People in these groups will get an IV infusion with different combinations of 2 study antibodies.

If you are eligible and agree to participate, you will have a visit where you receive the combination of antibody infusions. We will then ask you to come to the clinic about 3 days, 6 days, and 2 weeks after the infusion visit for physical exams and to draw your blood to look at how your body responds to the antibodies and to see how much of the antibodies are in your blood. There will then be other similar follow-up visits about 1-2 months apart for about a year since you received the combination of antibodies.

There are risks to taking part in any research study. These antibodies have been tested in small numbers of people in previous studies. Although there are other ongoing studies using these antibodies individually and in other combinations, there have been no studies in people using the same combinations of two antibodies as in this study. There may be side effects that we do not

yet know about, or side effects from these combinations which have not yet been given together, even serious ones.

There are different types of antibodies officially approved for use in preventing or treating other diseases. Those antibodies have caused fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, fatigue, flushing, trouble breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heartbeat, or chest pain.

Having blood drawn may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases fainting or infection. Placement of an IV catheter can cause bleeding, swelling, or bruising where the needle enters the body.

There will be no direct benefit to you if you participate in this study. This study may help in the search for a vaccine to prevent HIV.

Instead of volunteering to participate in this study, you have other choices. You may choose not to participate in this study.

If you are interested in learning more about this study, please continue reading the information presented below.

Information on Research

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.

Research Purpose

Why is this study being done?

The HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN) and Columbia University Medical Center are doing a study to test the combination of different antibodies against HIV. 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. Officially approved antibodies have been used successfully to prevent or treat some other health problems, such as a virus that causes respiratory infections in infants.

About 27 people will take part in this study at multiple sites. The researcher in charge of this study at this clinic is Dr. [redacted] Principal Investigator. The US National Institutes of Health (NIH) is paying for the study.

There are a total of 4 groups in this study. About 18 people total will take part in Groups 1, 2, and 3. After we see the safety results from Groups 1-3, we will decide whether or not to do Group 4. If we decide to do Group 4, 9 more people will join.

You are being invited to join Group 1, 2, or 3 of the study.

We are doing this study to answer several questions.

- Are the study antibodies safe to give to people in combinations?
- Are people able to take the study antibodies without becoming too uncomfortable?
- How much of the antibodies remains in the body as time passes?
- How does the body's response to the antibodies change depending on the combination given?

The study antibodies cannot give you HIV.

The study antibodies are not made from actual HIV. It is impossible for the antibodies to give you HIV. Also, they 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.

What are the risks of the study?

These study antibodies are experimental.

The formal names of the study antibodies are VRC07-523LS, PGDM1400, PGT121, and 10-1074. From here on, we will call them the study antibodies. They are experimental products. That means we do not know if they will be safe to use in people, or if they will work to prevent HIV infection. These study antibodies are used only in research studies.

The different study antibodies were developed by researchers at the Dale and Betty Bumpers Vaccine Research Center in Bethesda, Maryland, the Beth Israel Deaconess Medical Center in Boston, Massachusetts, and the Rockefeller Institute in New York, New York.

In laboratory studies, these study antibodies attached to and prevented infection by many kinds of HIV viruses from around the world. Each of the study antibodies was strongest against different varieties of HIV viruses. When combined in lab tests, they were able to prevent almost all varieties of HIV from infecting human cells.

In animal studies, the study antibodies prevented animals from infection with animal viruses that are very similar to HIV. The study antibodies have also been tested for safety in the laboratory and in animal studies.

We do not know if the study antibodies will prevent HIV infection when given to people. It will take many studies to learn if they will be useful for prevention of HIV infection. This study will not answer these questions.

These study antibodies have been tested in small numbers of people in previous studies. Although there are other ongoing studies using these antibodies individually and in other combinations, there have been no studies in people using the same combinations of two antibodies as in this study. There have not been any serious health problems in any of these studies so far.

Risks of the study antibodies:

This section lists the side effects we know about when the antibodies are given individually. There may be side effects that we don't yet know about, or side effects from these combinations, even serious ones. We will tell you about any new information that might change your willingness to stay in this study.

VRC07-523LS

The VRC07-523LS study antibody was given by injection or intravenous infusion (IV) to 25 people in a clinical trial at the NIH Clinical Center in Bethesda, Maryland. Two people who got the study antibody by IV had chills, fever, nausea, body aches, rapid heartbeat, and headache. These feelings went away within 12 hours.

As of October 2018, about 120 more people have gotten this study antibody by IV or injection in a clinical trial called HVTN 127/HPTN 087. This study is taking place at clinics in the US and in Switzerland. In this study, this antibody has not made people too uncomfortable or caused serious health problems so far.

A similar study antibody called VRC01 has been given to more than 3000 adults in several studies. Many of these studies are still going on and we don't know which people got the study antibodies and which got a placebo (a liquid with no antibody in it). After receiving the IV infusion or injection, many people said they had mild pain, itching, or redness where the antibody or placebo was given to them. Some of these people said they felt like they had the flu after getting the IV or injections, but this feeling lasted a few hours at most.

PGT121

The PGT121 study antibody is being tested in a study with HIV-positive and HIV-negative participants. As of July 2018, about 20 HIV-negative people and 14 HIV-positive people have gotten different doses of the study antibody by IV infusions and injections. Eight other people have gotten a placebo. There have been no serious health problems in any of the participants, and people have not found getting this study antibody or placebo too uncomfortable.

PGDM1400 and PGT121

The PGDM1400 study antibody is being tested by itself and in combination with the PGT121 study antibody. As of October 2018, 9 HIV-negative people have gotten PGDM1400 and 9 more HIV-negative people have gotten both PGDM1400 and PGT121. Six other people in this study have gotten a placebo. In this study people get the different doses of the study antibodies or a placebo by IV infusion. No serious health problems have been reported so far.

10-1074

The 10-1074 study antibody has been tested by itself and in combination with another study antibody. As of November 2018, 32 HIV-negative people have gotten different doses of 10-1074 by IV infusion. The most common problems people reported were upper respiratory tract infections (colds) and headaches. Only a few of these problems were possibly related to getting the study antibody. Most problems were mild.

General risks of antibodies:

There are different types of antibodies officially approved for use in preventing or treating other diseases. From all of these uses of antibodies, we know that most side effects happen within the first 24 hours. Those antibodies have caused fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, fatigue, flushing, 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 that may be life-threatening. These reactions may include:

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

These rare reactions have not been seen in other studies with similar experimental antibodies.

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 officially approved 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 antibodies in this study with 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 the study antibodies will stay in the body. We don't know yet how long they will last, but it may be several months.

Joining the study

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 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.

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 test you for syphilis, 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 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.

The law requires us to report positive HIV, hepatitis B, C and/or tuberculosis testing to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by New York State law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

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.

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 antibody could affect the developing baby.

You must agree to use effective birth control from 21 days before your first study infusion until 12 months after your last infusion.

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 infusion.

Being in the study

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

You will come to the clinic for scheduled visits about 13 times over about a year.

Most of the visits will be 1-2 months apart. We will also ask you to come to the clinic about 3 days, 6 days, and 2 weeks after the infusion visit to draw your blood. We will do this so that we can look at how your body responds to the study antibodies. We will also look at how much of the antibodies are in your blood. The infusion visit can last from 2 to 3 hours. Follow-up visits can last from 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).

We will give you some combination of two of the study antibodies.

People in Groups 1, 2, and 3 will get an IV infusion with different combinations of 2 study antibodies.

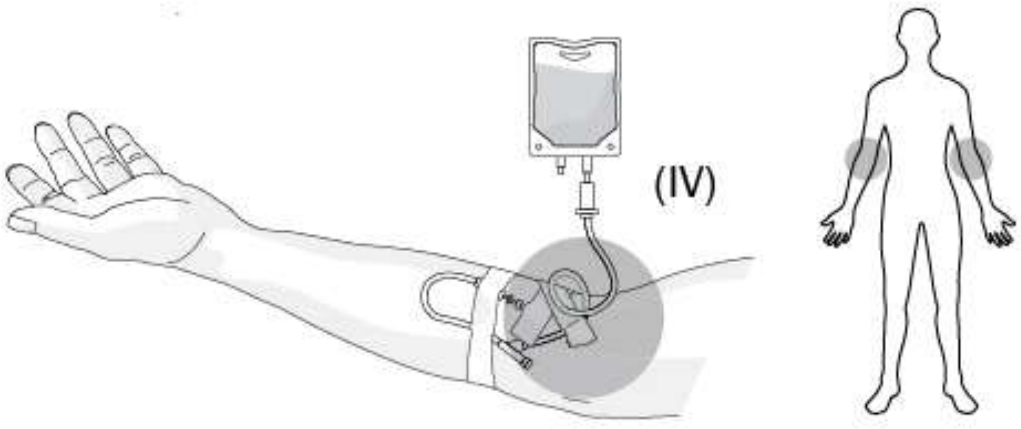
When getting an IV infusion, a sterile needle is used to place a small plastic tube into a vein in your arm. The tube is connected to a small container of fluid that contains the study antibody. Each antibody is in a separate container. An IV pump controls how fast the fluid drips from the container, through the tube, into your arm. The infusion will take about one hour for each study antibody (total of 2 hours).

Which group you are in and which antibody combination you get is completely random, like flipping a coin. We have no say in which group you are assigned to. Neither do you. You will know which antibody combination you will get.

We will give you the study antibodies on a schedule.

You will get the antibodies in a vein in your arm at one visit during the study. The antibodies will be given one at a time.

Schematic of IV Infusions



Infusion Schedule			
Group	Number of Participants	Study Antibodies	IV Infusion
1	6	PGT121 and VRC07-523LS	At enrollment
2	6	PGDM1400 and VRC07-523LS	
3	6	10-1074 and VRC07-523LS	

You will have to wait in the clinic for at least an hour after the infusion to see if there are any problems. We will collect a blood sample one hour after the IV. Then 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 about how to contact you. We will contact you about 3 days after the infusion visit 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.

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
- Ask questions about your experience getting infusions
- 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 25 mL and 100 mL (a little less than 2 tablespoons to a little less than ½ cup). Your body will make new blood to replace the blood we take out. Please tell us if you have blood drawn for other purposes during this study.

Table of Procedures - Groups 1 – 3

			Time after infusion									
Procedure	Screening visit(s)	Day 0	3 days	6 days	2 weeks	1 month	2 months	4 months	6 months	8 months	10 months	1 year
IV infusion		√										
Medical history	√											
Complete physical	√											√
Brief physical		√	√	√	√	√	√	√	√	√	√	
Urine test	√				√							
Blood drawn	√	√	√	√	√	√	√	√	√	√	√	√
Pregnancy test (participants assigned female sex at birth)*	√	√									√	
HIV testing and pretest counseling**	√							√		√		√
Risk reduction counseling	√	√			√	√	√	√	√	√	√	√
Interview/questionnaire(s)	√	√							√			√

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

** We will contact you with results of HIV testing.

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.

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.

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

We will send your samples (without your name) to labs approved by the HVTN and HPTN 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 and HPTN in other countries for research related to this study.

The samples will be tested to:

- Measure how much antibody is in your blood, and
- See how your immune system responds to the study antibodies.

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. We will ask you later in the consent form if you agree to any extra samples collected from you being used in the future for genome wide studies.

If you become HIV positive, 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).

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 with your permission.

When samples are no longer needed for this study, the HVTN and HPTN may want to use them in other studies and share them with other researchers.

These samples are called "extra samples". The HVTN and HPTN 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 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 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 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 will send your samples to the researcher's location.

What information is shared with HVTN, HPTN 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, monoclonal antibodies, the immune system and other diseases.

Researchers may also do genetic testing on your samples.

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.

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 and its study monitors,
- The US Food and Drug Administration,
- Any regulatory agency that reviews clinical trials,
- Authorities from Columbia University Medical Center and New York-Presbyterian Hospital, including the Columbia University Medical Center IRB
- Columbia University Medical Center staff and New York-Presbyterian Hospital staff
- The Dale and Betty Bumpers Vaccine Research Center, the Beth Israel Deaconess Medical Center, the Rockefeller Institute, and people who work for them,
- The HVTN, HPTN 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:

- Certain communicable diseases
- Suspected child abuse, or
- Suspected danger of physical or mental harm

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.

We may stop your infusion or take you out of the study at any time. We may do this even if you want to stay in the study.

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 infusion, we may ask you to stay in the study to complete other study procedures.

We will not give you an infusion if you become pregnant.

However, if you become pregnant after your infusion, 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.

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

We will encourage you to stay in the study for up to 4 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

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:

Collection of blood samples can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, blood clots, and (rarely) muscle damage, or infection. Taking blood can cause a low blood cell count (anemia), making you feel tired.

Risks of getting an IV infusion:

Getting an infusion 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.

Personal problems/discrimination/testing HIV antibody positive:

Some people who join HVTN and 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. We have used several common HIV antibody tests to test samples of blood containing different amounts of one of the study antibodies, VRC07-523LS. These tests show that very high levels of this antibody 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. We don't know if the different brands of tests will have similar results for the other antibodies.

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

Because of these risks, you should 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 not HIV infected. We do not expect you to have any problems with HIV testing after the study ends because the antibodies do not last in the body for that long.

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

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

Benefits

The study may not benefit you.

We do not expect that getting the study antibodies will 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 gets approved and sold, there are no plans to share any money with you.

We will give you the following compensation for each study visit you complete.

- $25 for screening education visits
- $200 for the one-time infusion at enrollment (Day 0)
- $75 for scheduled study visits where you give blood
- $25 for scheduled study visits that do not involve any blood collection

You will receive approximately $1000 (amount not exact) in total while you take part in the study. You will not receive compensation for any study visits you do not attend.

You will receive compensation through a reloadable debit card, which will be provided to you.

This "reloadable" card is NOT anonymous. For these cards, we would register you with the vendor of the debit cards, Bank of America (BOA) by providing your name, address, and phone number. You would receive one card, which would be "reloaded" after each completed study visit. This card can be used as a credit card OR as an ATM card. You would be able withdraw money from a bank either through a bank teller or an ATM machine. Please note that banks may charge a fee for using their ATM machine. If you lose the card, you *can* contact BOA and have the card replaced. Please read the information sheet that comes with the card for more information.

This amount is to cover the costs of time and travel. According to IRS regulations, payments totaling more than $600 in a calendar year are considered taxable compensation and will be reported to the Internal Revenue Service (IRS). Payment for taking part in a research study may be considered taxable income.

If payment for this study is more than $600.00 in any one calendar year, the study doctor or clinic will have to report this to the Internal Revenue Service (IRS). This will be reported using a 1099 (Miscellaneous Income) form. This form will be issued to you and a copy will be sent to the IRS. If this is done, we will need your social security number in order to process the payment with a statement that you are being reimbursed for participating in a clinical trial. However, the name of the clinical trial or a description of the research will not be identified. There is a potential loss of confidentiality due to interactions with the Office of the Treasurer and a delay of receipt of payment.

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

Additional Costs

There will be no cost to you for the study drugs, the study-related visits, physical examinations, laboratory tests or other tests required by the study. You or your insurance company, or your health care system will be responsible for the costs of your regular medical care as well as for the costs of drugs not given by the study.

You will remain responsible for all insurance premiums, deductibles, copayments, and coinsurance.

Your rights and responsibilities

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

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

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

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the New York-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by you, your health insurance, covered by the HVTN, or covered by other groups, depending on a number of factors. For example, the HVTN has limited funds to pay medical costs that it determines are reasonable.

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, none of the HVTN, Columbia University, New York-Presbyterian Hospital, or other groups are offering funds to pay for these kinds of injuries, even if they are study related.

Columbia University Medical Center, New York-Presbyterian Hospital (NYPH) and the U.S. National Institutes of Health (NIH) are not offering to provide you the study vaccines after the termination of the study or to pay you for pain, worry, lost income, or non-medical care costs that might occur as a result of your taking part in this study. In addition, Columbia University, New York-Presbyterian Hospital is not offering to cover the cost of your medical care.

However, you do not waive any of your legal rights in signing this form.

You may disagree with the decision about whether your injury is study related. If you wish, the HVTN will ask independent experts to review the decision.

Questions

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

For questions about this study contact:

Dr. [redacted] at [redacted], or the study coordinator at [redacted].

If you have a research-related sickness or injury contact:

Dr. [redacted] at [redacted], or the study coordinator at [redacted]

If an emergency occurs during non-business hours, please page Dr. [redacted] at [redacted] or call [redacted].

For questions about your rights as a research subject, or problems or concerns about how you're being treated in the study, contact:

Institutional Review Board
Columbia University Medical Center
[redacted]
[redacted]
Telephone: ([redacted]

To withdraw from the study, contact the Principal Investigator, Dr. [redacted] or the study coordinator via telephone or in person to notify that you would like to withdraw from the study.

Your permissions and signature

Statement A

Please initial the appropriate statement to indicate whether or not you give permission for the researchers and/or study staff to contact you and/or your primary healthcare provider in the future for:

YES_____ NO_____ Information relating to this study

In Section 14 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 and HPTN 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.

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 or genome wide studies.

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.

You will receive a copy of this signed and dated consent form.

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

_____	_____	_____	_____
Clinic staff conducting consent discussion (print)	Clinic staff's signature	Date	Time

<u>For participants who are unable to read or write</u>:

We plan to follow the IRB and State policy with respect to enrolling individuals who may be physically unable to read or write, but only if you are able to give consent and indicate understanding the risks and benefits of participating. If we encounter a situation analogous to this, we will document the means by which you indicated consent and your understanding of study procedures and a witness signature will be obtained.

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

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