HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA
CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Protocol Title:	**HVTN 104: A phase 1 clinical trial to evaluate the safety and drug levels of a human monoclonal antibody, VRC-HIVMAB060-00-AB (VRC01) administered in multiple doses intravenously and subcutaneously in different dosing schedules to healthy, HIV-uninfected adults**
Principal Investigator:	Ian Frank, MD 3535 Market St., 4th floor, Ste 4000 215 662-7419
Co Investigators	Pablo Tebas, MD 215 349-8092 215 746-7346 Debora Dunbar, MSN, CRNP 215 746-3713
Lead Study Nurse:	Mark Bardsley, RN, BSN 215 349-8092
Research Team:	Wayne Wagner, RN, MSW Aleshia Thomas, RN, BSN Joseph Quinn, RN, BSN Yan Jiang, RN, BSN, MSN
Research site address	Screen visits: 3535 Market St., 4th floor, Ste 4000 Enrollment and On-study: HUP, Clinical Research Center 1 Dulles
24 hr. Emergency Contact:	*Immunodeficiency Program Doctor on call* *(215) 662-6059*

Introduction:

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 The University of Pennsylvania are doing a study to test an antibody 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. Antibodies can also be manufactured like a drug and infused or injected into the body. This approach has been successfully used to prevent or treat some other diseases.

About 64 people will take part in this study at multiple sites. At PENN, we anticipate enrolling about 16 people. The researcher in charge of this study at this clinic is Ian Frank, MD. The US National Institutes of Health (NIH) is paying for the study.

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

    - Are the study products safe to give to people?
    - Are people able to take the study products without becoming too uncomfortable?
    - How do people's bodies respond to the study products?
    - How much of the antibody remains in your body as time passes?
    - How does the body's response to the study products change depending on the amount and timing of the doses?
    - Does the method of giving the antibody change the body's response?

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

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

3. **These study products are 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. We will also be testing the placebo. The placebo is made from inactive ingredients made to look like the antibody. Together we will call them the study products.

They are experimental. That means we do not know if they will be safe to use in people, or if the antibody will work to prevent HIV infection. They are used only in research studies.

The study products were developed by the NIH. They were both made using the controlled, sterile conditions used for drug manufacturing.

In laboratory and animal studies, VRC01 attached to and disabled many kinds of HIV viruses. We do not know if the antibody will act the same way when given to people. It will take many studies to learn if the products will be useful for prevention of HIV or treatment of HIV. This study alone will not answer these questions.

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 other HIV vaccine or HIV prevention studies now or in the future. You cannot be in this study while you are in another study where you receive 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 decide 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, and height, 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

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 ask you about medications you are taking. We will also test you for syphilis, Hepatitis B, and Hepatitis C. We will ask you about behaviors that might put you at risk for getting HIV. If you were born female, we will test you for pregnancy. People who have had a complete hysterectomy (removal of the uterus and ovaries, verified by medical records), are not required to have a pregnancy test.

We will review the screening results with you, and offer you counseling and referral if you need medical care. We will not pay for this medical care. The screening results may show you are not eligible to join the study, even if you want to. You will be asked to attend two screening visits.

6. If you are a female who 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 products could affect the developing baby. You must agree to use effective birth control from 21 days before you first receive study products until your last required clinic visit. We will talk to you about effective birth control methods. They are listed in Appendix A of this consent form. If you join the study, we will test you for pregnancy at some visits.

Being in the study

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

7. You will come to the clinic for scheduled visits about 11-18 times over about 8 months depending on which group you are in.

Visits can last from 1 to 3 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).

8. We will reimburse for each study visit you complete.

This amount is to cover the costs associated with your participation and transportation. If we give you a ride, we will not give you a token for that part of your transportation.

We will give you $50.00 for each screening visit you complete along with two septa tokens. We will give you $100.00 and two SEPTA tokens for each study visit you complete once you are enrolled. If you are in Group 1 the total compensation received is $1200; Group 2, $1100 and Group 3; $1800.

We will give you $25.00 and two SEPTA tokens for visit which are solely to receive your HIV test results. If the research staff requests that you come in for an extra visit to have a lab test repeated or an adverse event evaluated, you will be paid $50 for that visit.

If you choose to participate in the mucosal secretion optional study (collection of saliva, rectal and semen or cervical samples) we will pay you $25 for EACH sample provided at EACH of the three time points.

We will pay you $10 up to one time a month to update your locator information by visiting the clinic since it is important that you keep us informed of how to find you.

We will pay you with a check. If you use a fee for service check cashing agency, we will add $1 to the check to cover your check cashing fee.

Payments you receive for being in the study may be taxable. This happens if we pay you more than $600 between January 1 and December 31 of the same year. The clinic staff 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.

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

You will be in one of 3 groups. Each group will have a different schedule for getting the antibody or placebo and will receive different doses of the antibody or placebo.

Groups 1 and 2

People in Groups 1 and 2 will get all of their doses by intravenous (IV) infusion. IV infusion is done by putting a needle into a vein in your arm.

- **Each IV infusion will take about one hour.**
- You will have to wait in the clinic for about another hour after each infusion to be sure you don't have any problems.

Group 3

People in Group 3 will get their first dose by IV infusion but the other doses by subcutaneous (SC) injection. SC injections are done by putting a needle under the skin on your arm, abdomen or thigh.

- **The first dose by IV infusion will take about one hour.**
- You will have to wait in the clinic for about another hour after the infusion to be sure you don't have any problems.
- The subcutaneous (under the skin) injections will only take a few minutes.
- Depending on the size of the dose, we may need to give you 2 subcutaneous injections at each visit.
- You will have to wait in the clinic for about an hour after the first subcutaneous injection to be sure you don't have any problems.
- If you don't have any problems with the first subcutaneous injection, you will only have to wait in the clinic for about ½ hour after the rest of the injections.

The high, medium, and low doses of the study products that are used in all groups will be adjusted for your body weight. We will weigh you on the day of each dose to determine the amount you will get.

On the night of your injection or infusion and for three more days, you will need to write down how you are feeling and if you have any symptoms on a diary card that we will give you. The clinic staff will talk with you each of these days to collect the information recorded on your diary card. You will be provided with a 24 hour number, and can contact the clinic staff if you have any issues or concerns after receiving an infusion or injection. If you have a problem, we will continue to check on you until it goes away.

		Infusion and Injection Schedules											
			Time after the 1st visit										
Group	**Number of people**	**1st visit**	**2 weeks**	**1 month**	**1.5 months**	**2 months**	**2.5 months**	**3 months**	**3.5 months**	**4 months**	**4.5 months**	**5 months**	**5.5 months**
1	20	VRC01 high dose by IV		VRC01 medium dose by IV		VRC01 medium dose by IV		VRC01 medium dose by IV		VRC01 medium dose by IV		VRC01 medium dose by IV	
2	20	VRC01 high dose by IV				VRC01 high dose by IV				VRC01 high dose by IV			
3	20	VRC01 high dose by IV	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC	VRC01 low dose by SC
	4	placebo IV	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC	placebo SC
Total	64												

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

Not everyone in this study will get the antibody.

Groups 1 and 2:

All of the people in groups 1 and 2 will get the antibody.

Group 3:

20 of the people in group 3 will get the antibody. The other 4 people in group 3 will get the placebo.

In Group 3, there is one placebo for the infusion given by IV, and another placebo for the SC injection. Neither you nor the clinic staff will know if you are getting the antibody or placebo. Only the pharmacist at your site will have this information while the study is going on. We will compare the results from people who got the placebo with results from people who got the antibody.

We will also compare the results from people who got the antibody in all 3 groups.

If you are in Group 3, you will have to wait until everyone completes their final study visits to find out whether you got the antibody or the placebos. This could be more than a year. 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.

11. You will be assigned to a group.

Based on your screening visit and schedule, you and the study staff will discuss which group is best for you. Group 3 has more study visits, so you will need to decide if this fits your schedule. If you prefer a less frequent visit schedule, we will assign you to Group 1 or 2 randomly, like flipping a coin. You will be in the same group the whole time you are in the study. The charts below summarize the visits for each group; in the next sections of the consent these visits are detailed.

Group 1

Procedure	Screening visit	First infusion visit	Time after first infusion										
			3 days	2 weeks	1 month	1 month + 3 days	1½ months	2 months	3 months	4 months	5 months	6 months	8 months
IV Infusion		√			√			√	√	√	√		
Medical history	√												
Complete physical	√												√
Brief physical		√	√	√	√	√	√	√	√	√	√	√	
Urine test	√			√					√			√	
Blood drawn	√	√	√	√	√	√	√	√	√	√	√ (2x)[d]	√	√
Pregnancy test (participants born female)[a]	√	√			√			√	√	√	√	√[e]	√
HIV testing & pretest counseling	√								√			√	√
Risk reduction counseling	√	√	√	√	√	√	√	√	√	√	√	√	√
Interview/ questionnaire	√	√	√	√	√	√	√	√	√	√	√	√	√
Pap smear (if needed)[b]													
Cervical fluid sample (optional)									√			√	√
Rectal fluid sample (optional)									√			√	√
Semen sample (optional)									√			√	√
Saliva sample (optional)									√			√	√

Group 2

Procedure	Screening visit	First infusion visit	Time after first infusion								
			3 days	2 weeks	1 month	2 months	2 months + 3 days	3 months	4 months	6 months	8 months
IV Infusion		√				√			√		
Medical history	√										
Complete physical	√										√
Brief physical		√	√	√	√	√	√	√	√	√	
Urine test	√			√				√		√	
Blood drawn	√	√	√	√	√	√	√	√	√ (2x)[d]	√	√
Pregnancy test (participants born female)[a]	√	√				√		√	√	√[e]	√
HIV testing & pretest counseling	√							√		√	√
Risk reduction counseling	√	√	√	√	√	√	√	√	√	√	√
Interview/ questionnaire	√	√	√	√	√	√	√	√	√	√	√
Pap smear (if needed)[b]											
Cervical fluid sample (optional)								√		√	√
Rectal fluid sample (optional)								√		√	√
Semen sample (optional)								√		√	√
Saliva sample (optional)								√		√	√

Group 3

Procedure	Screening visit	First infusion visit	Time after first infusion															
			3 days	2 weeks	2 weeks + 3 days	1 month	1½ months	2 months	2½ months	3 months	3½ months	4 months	4½ months	5 months	5½ months	5½ months + 3 days	6 months	8 months
IV Infusion		√																
SC injection				√		√	√	√	√	√	√	√	√	√	√			
Medical history	√																	
Complete physical	√																	√
Brief physical		√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
Urine test	√			√						√							√	
Blood drawn	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Pregnancy test (participants born female)[a]	√	√		√		√	√	√	√	√	√	√	√	√	√		√[c]	√
HIV testing & pretest counseling	√									√							√	√
Risk reduction counseling	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Interview\ questionnaire	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Pap smear (if needed)[b]																		
Cervical fluid sample (optional)										√							√	√
Rectal fluid sample (optional)										√							√	√
Semen sample (optional)										√							√	√
Saliva sample (optional)										√							√	√

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;
- Perform physical exams;
- Take blood and urine samples;
- Do pregnancy tests if you were born female; people who have had a complete hysterectomy (removal of the uterus and ovaries, verified by medical records), are not required to have pregnancy tests;
- Ask questions about your health, including medications you may be taking;
- Ask questions about your experience of getting the antibody or placebo;
- Ask questions about any personal problems or benefits you may have from being in the study.

When we take blood, the amount will depend on the lab tests we need to do. It will be some amount between 10 mL and 100 mL (less than 1 tablespoon to about 1/2 cup). Your body will make new blood to replace the blood we take out.

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 also offer you counseling and referral for needed care.

13. If you agree, we will also collect saliva, rectal and semen or cervical samples.
Since HIV exposure can occur in the mouth, rectum, penis, or vagina, it is important to learn if antibodies are found in these locations after getting infusions or injections. For this reason, we want to collect saliva, rectal and semen or cervical samples to look for antibodies. We will collect these samples at 3 visits. We will do this only if you agree and are able to provide the samples.

At the end of this consent form, we will ask if you allow us to collect these samples. You can decide not to give us these samples and still be in the study. You can decide to provide some of these samples and not others. If you agree to provide these samples, you can change your mind at any time during the study.

About saliva samples

For participants who agree to give saliva samples, we will ask you to spit into a container. We want to collect about a teaspoon of saliva. Please avoid the following for 1 hour before your visit:

- smoking,
- eating,
- chewing gum or tobacco,
- drinking anything but water ,
- intimate oral activity, and
- brushing your teeth or using mouthwash.

About rectal samples

For participants who agree to give rectal samples, we will collect rectal fluids by placing a small absorbent sponge in the rectum using a plastic tube about as wide as a pencil. This will take about 5 minutes. We will not collect the sample if you have an active infection, inflamed hemorrhoids, or colitis/diarrhea. We will:

- perform a pregnancy test for participants born female; people who have had a total hysterectomy (removal of the uterus and ovaries, verified by medical records), are not required to undergo pregnancy testing. We do not do most study procedures on pregnant women, so we will do a pregnancy test first.
- not collect the sample if you have had receptive anal intercourse or inserted anything into your anus for 48 hours (2 days) before the visit.
- not collect the sample if you have used steroids or other anti-inflammatory creams in or around your anus for 48 hours (2 days) before the visit.

About semen samples

For eligible participants who agree to give semen samples, you may provide the samples at home or at the clinic. We will ask you:

- to ejaculate into a plastic cup that we will give to you.
- to bring the semen sample to the clinic within 2 hours after collection, if the sample is collected outside of the clinic.

About cervical samples

For eligible participants who agree, we will collect cervical fluid. To collect cervical fluid, we will insert a speculum (a device that opens the vagina) into your vagina. Then we will place a small sponge in the opening of the cervix for about a minute to absorb the fluid. We will not collect the sample if you have any active genital infections or sores. We will:

- perform a pregnancy test for participants born female; persons who have had a total hysterectomy (removal of the uterus and ovaries, verified by medical records), are not required to undergo pregnancy testing. We do not do most study procedures on pregnant women, so we will do a pregnancy test first.
- not collect the sample if you are menstruating.
- not collect the sample if you have had vaginal intercourse or inserted anything into your vagina for 48 hours (2 days) before the visit.
- not collect the sample if you have used any spermicide, lubricants or topical/intravaginal medications (such as topical yeast infection treatments), including douching, within 48 hours (2 days) before the visit.
- require a Pap smear if you have not had one within 3 years before enrollment, with the latest result reported as normal. We can give you a Pap smear if you have not had one within that timeframe.

14. We will counsel you on avoiding HIV infection.

We will ask you personal questions about your HIV risk factors such as sexual behavior and drug use. We will talk with you about ways to keep your risk of getting HIV low. Some topics we may discuss include:

- What you think may cause risky behavior for you.
- Methods to avoid getting HIV.

15. We will test your samples for this study.

We will send your samples (without your name) to a lab to see how your body responds to the antibody or placebo. The researchers may:

- Take cells from your samples and grow more of them. We may grow more of your cells over time, so that they can continue to contribute to this study.
- Do limited genetic testing. Your genes are passed to you from your birth parents. They affect how you look and how your body works. The difference in people's genes can help explain why some

people get a disease while others do not. Limited genetic testing involves only some of your genes, not all of your genes (your genome). The researchers will not look at all of your genes, only the genes related to the immune system and diseases.

- These tests are for research purposes only. The lab will not give the results to you or this clinic, and the results will not become part of your study record.

16. When we take samples from you for this study, we take extra samples in case we have to repeat tests. When samples are no longer needed for this study, the HVTN wants to keep them for use in other studies. 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 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. The central repositories for the HVTN are located 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 sell my samples and information? No, but the HVTN 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. 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. The HVTN keeps track of your decision about how your samples and information can be used.

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 products you received and how your body responded to the study products.

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. The researchers may:

- Take cells from your samples and grow more of them. This means the researchers may keep your cells growing over time.

- Do limited genetic testing, which involves only looking at some of your genes, not all of your genes.

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
- 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.

Risks

17. There are risks to being in this study.

There are risks associated with the antibody, VRC01 and there are 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 VRC01:

VRC01 has been given to more than 25 people in clinical trials at the NIH Clinical Center. The study products have been tested in one study with HIV-positive people and in one study with HIV-negative people. So far the antibody is well tolerated with no or mild side effects. When injected into skin there may be mild redness, swelling, and itching at the injection site that resolves within a few minutes to hours.

With antibody products, most side effects tend to occur within the first 24 hours.

In a study where VRC01 was given to animals, there was a small increase in two liver lab tests. This increase lasted for a short period of time. No sign of liver damage was seen in the animals. There were no abnormal findings in the animals' organs except for irritation at the location where the antibody was given.

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

Some antibody products have a small risk of causing serious drug reactions. These reactions may be life-threatening.

- One type of reaction may occur soon after an antibody product is given. It includes difficulty breathing possibly leading to low blood oxygen, low blood pressure, hives or rash, and/or swelling in the mouth and face.
- A second type of reaction may occur several days to three weeks after an antibody product is given. It includes having hives or a rash, fever, big lymph nodes, muscle pains, joint pains, chest discomfort and shortness of breath.
- When antibodies are given to a person by infusion or injection they do not last in the body more than a few months. Any antibody given to you in this study will be gone from your body several months after your last dose.

Risks of placebo:
The placebo does not contain antibodies and is made of inactive ingredients. These are generally recognized as safe but there may be unknown risks associated with the placebo.

Risks of routine medical procedures:
In this study, we will do some routine medical procedures like taking blood. These procedures can cause bleeding, bruising, pain, fainting, soreness, redness, swelling, itching, muscle damage, and (rarely) infection where the needle was inserted or blood clot. Taking blood can cause a low blood cell count (anemia), making you feel tired.

Risks of IV infusion and SC injection procedures:
Receiving an infusion or injection through a needle may cause stinging, discomfort, pain, soreness, redness, bruising, itching, rash and swelling at the location where the needle goes into the skin. Rarely, needlesticks can result in infections.

We will ask you to stop some behaviors related to your mouth, rectum, and genitals for a short time before we collect samples from these areas. You may find this inconvenient. These sample collections may also cause some anxiety, temporary discomfort, and embarrassment. For women, the collection of cervical fluid may cause discomfort similar to what happens during a Pap smear. We will try to make you as comfortable as possible.

Personal problems/discrimination/testing HIV antibody positive:

About 10 to 20% of people who join HVTN studies report personal problems or discrimination because of joining an HIV vaccine study. Although this is not a vaccine study, it may raise similar concerns. 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.

If someone assumes you are infected with HIV, even if you are not, you could face discrimination and other problems. For example, you could be denied medical or dental care, employment, insurance, a visa, or entry into the military. Your family and friends may treat you differently.

An HIV antibody test is the usual way to test for HIV infections. In HIV vaccine studies, getting the study vaccine can cause you to test positive on some types of HIV antibody tests. This study is different, because you will not get an HIV vaccine. Based on lab tests, we do not expect the study product to cause a positive result on standard HIV antibody tests. However, we still ask you to get HIV tests only at this clinic during the study. Our tests can always tell the difference between true HIV infection and a positive result that is caused by a study product.

If you become pregnant while you still have the antibody in your body, we don't know if this antibody could be passed to your baby.

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.

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 products will increase, decrease, or not change your risk of becoming infected with HIV if you are exposed to the virus. If you get infected with HIV, we do not know how the study products might affect your HIV infection or how long it takes to develop AIDS.

We do not know if getting these study products will affect how you respond to a future approved HIV vaccine. It could be that a future HIV vaccine may not work as well for you because you got these study products. Currently, no HIV vaccine has been approved for use.

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

Benefits

18. The study may not benefit you.

We do not expect that getting the study products 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 way to prevent HIV. However, if the study products later become approved and sold, there are no plans to share any money with you.

Confidentiality

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

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

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

- The name of your study,
- Your age or date of birth,
- Your study ID number,
- What study products you received.

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

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

- The US National Institutes of Health and its study monitors,

- The US Food and Drug Administration,
- The University of Pennsylvania Institutional Review Board (IRB) ,
- National Institutes of Health 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:

By law we have to report your HIV infection (if you test positive) to the City of Philadelphia Health Department. We would report your name, gender, racial/ethnic background, and the month and year you were born. This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

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.

When the study is done, we may share the information from the study with others so they can see it and use it. We will not share any information that will let someone identify you.

There are reasons for asking you for your personal contact and health information.
The research study staff needs your personal contact information to find and contact you during the study. The staff collects your personal health information and results of tests and procedures as part of this research study. Your personal health information may also be used to help guide your medical care.

- Name, address, telephone number, date of birth, MRN, email address
- Social Security Number (if you receive more than $600 for participating in studies at PENN, we will need your SSN for the W-9)

- Personal and family medical history
- Current and past medications or therapies
- Results of physical exams, laboratory tests and procedures you will undergo during this research study

These members of our staff may use or make your personal health information known to others:
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 include:

- The Principal Investigator and the Investigator's study staff
- Authorized members of the staff of the UPHS and the School of Medicine and University of Pennsylvania office staff who may need to know your information to perform their jobs (for example, to manage study payment records, etc.)
- The University of Pennsylvania Institutional Review Board, the University of Pennsylvania Office of Regulatory Affairs, and the University of Pennsylvania Office of Clinical Research (groups at the University that make sure your rights are protected while you are in the study)

The following groups outside of UPHS and the School of Medicine might receive your personal health information.
As part of the study, the Principal Investigator, the study staff and others listed above, may make known your personal health information, including the results of the research study tests and procedures. This information may be made known to individuals or organizations responsible for helping with the study work and monitoring the study. These include:

- Staff of the study sponsor, the Division of AIDS (DAIDS), a Division of the National Institute of Allergies and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH), (a government agency in Bethesda, MD) and people or companies working for the sponsor, who will send the study results to the U.S. Food and Drug Administration (FDA)
- The U.S. Office of Human Research Protections (OHRP) a government agency that oversees the safety and effectiveness of this research
- Staff of the HIV Vaccine Trials Network (HVTN) and people or companies working for the HVTN, an organization running this study for DAIDS here and at some other sites in the US and other countries, who manage the study and study data and report the study results
- The HVTN Safety Monitoring Board and the NIAID Data and Safety Monitoring Board
- The Members of the Institutional Review Office of the Fred Hutchinson Cancer Research Center, who are reviewing this study
- Labs handling specimens: Children's Hospital of Philadelphia Clinical Labs, Fred Hutchinson Cancer Research Center/University of Washington, University of Pennsylvania and other labs hired by the study sponsor to do lab tests and analyze results for the study
- Staff of Pharmaceutical Product Development, Inc. (PPD), an agency hired by the sponsor to review study procedures and data and correct any mistakes before the results are given to the study sponsor and government agencies funding and/or monitoring study safety

Once your personal health information is given to others outside of the University of Pennsylvania Health System (UPHS) or School of Medicine, it may no longer be covered by federal privacy protection regulations. However, anytime that we give your information to outside groups or agencies:

- it will not include your name, social security number, address, telephone number, other contact information or any other personal identifying information unless it is required by law
- It will be assigned a unique code number. The Principal Investigator and his staff will keep the information that links your name to the code in a locked file cabinet and in a password-protected computer file
- All reviewers will take steps to keep your records private

The Principal Investigator or study staff will inform you if there are any additions to the list above while you are in the study. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

You may not be able to access some of your records.
While you take part in this study, you might not be able to see or get some of your research medical exam or test results. This is because by knowing your study results, you could affect the reliability of the study. You will be able to get this medical record information when the study is over, or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

You can change your mind.
At any time you may decide that you do not want us to use and make known your personal health information as described here. You must do so by writing to the Principal Investigator at the address on the first page. However, any personal health information that was collected before we received your written request may still be used and made known to others as needed for the study. If you decide to no longer allow us to use your personal health information, you will not be able to stay in the research study. You will be given a copy of the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

Your authorization for use of your personal health information for this study does not expire or end.
We may hold your information in a research storage file or database. However, UPHS and the School of Medicine may not re-use or make known information collected in this study for a purpose other than this study unless:

- You have given written permission to do so
- The University of Pennsylvania's Institutional Review Board allows it after making sure that the proper privacy safeguards are in place
- As permitted by law

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

Each of the groups who watch over this study may review your medical records. Your study records may also be reviewed by clinic staff. Reviewers will keep your records private.

20. We may stop your infusions or injections or take you out of the study at any time. We may do this even if you want to stay in the study and even if you were scheduled for additional infusions or injections.

This may happen if:

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

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

21. If you become pregnant during the study, we will continue with some procedures but not infusions or injections.

We will do this for as long as it is safe for you and your developing baby.

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

You will not be able to stay in this study. 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, and about other studies you may want to join. We will not provide or pay for any of your HIV care directly.

Your rights and responsibilities

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

Leaving the study

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

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

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

Injuries

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

Your health is important to us. We will help you get the medical care you need.

You could get sick or injured by the study products and/or procedures. If this happens, the HVTN has limited funds from the U.S. government to pay for your treatment.

If someone gets sick or injured in an HVTN study, the HVTN decides whether the injury is probably related to the study products and/or procedures. If the HVTN decides it was more likely due to the study products and/or procedures than any other cause, then the HVTN will use its funds to pay for treatment. The HVTN expects to cover the entire costs for the treatment of simple, temporary study related injuries. If your injuries are more severe or chronic, the HVTN funds may not be enough. If needed, the HVTN will seek more funds, but cannot guarantee them. If the HVTN cannot pay the entire cost of your treatment, you or your health insurance company would be responsible for any additional costs. Some health insurance companies will not pay for study related injuries.

If the HVTN decides the injury is likely not due to the study products and/or procedures, then you or your health insurance would be responsible for treatment costs. You may disagree with the decision the HVTN makes about your injuries. At your request the HVTN will ask experts who are not connected with the HVTN to review its decision. No matter what, you still have the right to use the court system to address payment for your injuries if you are not satisfied.

Some injuries are not physical. For example, someone might be harmed psychologically or emotionally by being in an HIV related study. Or they might lose wages from injuries because they could not go to work. No funds have been set aside to pay for nonphysical injuries, even if they are related to participation in the study.

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 Debora Dunbar at (215) 746-3713.

If you have any symptoms that you think may be related to this study, contact Debora Dunbar at 215-746-3713.

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 Director of Regulatory Affairs at the University of Pennsylvania by phoning 215-898-2614.

If you want to leave this study, contact Debora Dunbar at 215-746-3713.

Your permissions and signature

In Section 13 of this form, we told you about collecting saliva, rectal, and semen or cervical samples. Please write your initials or make your mark in the boxes next to the options you choose.

☐ I agree to provide rectal samples.

☐ I do not agree to provide rectal samples.

☐ I agree to provide semen or cervical samples.

☐ I do not agree to provide semen or cervical samples.

☐ I agree to provide saliva samples.

☐ I do not agree to provide saliva samples.

In Section 16 of this form, we told you about possible other uses of your extra samples and limited information, outside this study. Please write your initials or make your mark in the box next to the option you choose.

☐ I allow my extra samples combined with limited information for other studies related to HIV, the immune system, and other diseases. This may include limited 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 the genome wide studies.

OR

☐ I do not allow my extra samples to be used in any other studies. This includes not allowing limited genetic testing, growing more of my cells, 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.

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.

Appendix A Approved birth control methods

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

If you were born female and are sexually active in a way that could lead you to get pregnant, you must agree to use effective birth control from 21 days before your first injection or infusion until after your last required clinic visit.

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 female partner or partners;

☐ You only have oral sex; or,

☐ You are sexually abstinent (no sex at all).

Remember: If you are having sex, you need to use male or female condoms to protect yourself from HIV infection.