

HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND RESEARCH SUBJECT HIPAA
AUTHORIZATION**

Protocol Title: **A5340, Version 2.0, 05/12/15, Letter of Amendment 2 4/21/16:**
A Phase I, Open-Label Study of the Safety, Pharmacokinetics, and Antiviral Activity of a Human Monoclonal Antibody, VRC-HIVMAB060-00-AB (VRC01), with Broad HIV-1 Neutralizing Activity, Administered Intravenously to HIV-Infected Adults Undergoing a Brief Analytical Treatment Interruption
A DIVISION OF AIDS/ AIDS CLINICAL TRIALS GROUP (ACTG) Study

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Introduction:

You are being asked to take part in this research study because you are infected with the Human immunodeficiency virus (HIV), the virus that causes AIDS and because you are taking anti-HIV drugs that are controlling your HIV infection. This study is sponsored by the National Institutes of Health (NIH). The doctor in charge of this study at this site is: Dr. Pablo Tebas. Before you decide if you want to be a part of this study, the A5340 team wants you to know about the study.

This is a consent form. It gives you information about this study. The study staff will talk with you about this information. You are free to ask questions about this study at any time. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. If you agree to take part in this study, you will be asked to sign this consent form. You will get a copy to keep.

Why Is This Study Being Done?

Antiretroviral therapy (ART) in HIV infected people helps to stop the virus from multiplying and the goal of treatment is to have such a small amount of the virus in your blood that it does not show up on tests. The problem is that HIV is also hidden in cells throughout the body and can once again start multiplying when ART is stopped. This creates a challenge as we begin to explore how HIV infection might be cured.

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Antibodies, found naturally in your body, help protect the body against foreign matter such as bacteria and viruses. Recently, an antibody called VRC01 has been found to reduce the amount of HIV virus in animal studies as well as in a few human studies. There are human studies going on using VRC01 in people who are not infected with HIV to see if it is safe and if it causes side effects. VRC01 is an investigational drug and that it has not been approved for commercial use by the Food and Drug Administration. The purpose of this study is to see if infusions of the monoclonal antibody given three times, 21 days apart are safe and effective at keeping HIV viral loads undetectable even when oral HIV medications are stopped. If VCR01 is found to be safe, then other studies can be done to see if it helps reduce the amount of virus found in people infected with the HIV virus.

How Many People Will Take Part in This Study?

About 15 people will take part in this study and will enroll at two centers in the ACTG. About 8 people are expected to enroll at the University of Pennsylvania.

How Long Will I Be In This Study?

You may be in this study for about 6-9 months if you agree to participate in the optional evaluations. If you do not participate in the optional evaluations, you will be in this study for 6 months.

What Do I Have To Do If I Am In This Study?

All visits for this study will take place in the CTRC (1 Dulles) at the Hospital of the University of Pennsylvania. If you decide to take part in this research study, you will be asked to sign this consent form and schedule a screening visit to determine if you can join the study. This visit will occur prior to being given any study medications.

In this study we will ask you to stop taking your antiretroviral medicines for 8 weeks and receive 3 doses of VCR01 several weeks apart. During the time you are off of your ARVs, we will carefully monitor your CD4 cell count and viral load to see if it causes you any side effects. Other safety tests will also be performed and tissue samples will be taken. More details are provided below.

Evaluation or test	Screen	Pre-Entry	Entry	Analytical Treatment Interruption (Study week)									Weekly until viral load >1000 or CD4 <350	Early discontinuation
				1	2	3	4	5	6	7	8	9		
Consent	✓													
Clinical assessments	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Administration of VRC001			✓			✓			✓					
Hematology	✓	✓	✓	✓		✓	✓		✓		✓		✓	✓
Chemistry and LFTS	✓	✓	✓	✓			✓				✓		✓	✓
CD4 count	✓	✓	✓		✓		✓		✓		✓		✓	✓
Viral load	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pregnancy test	✓		✓			✓			✓					
Leukapheresis		✓										✓		
Rectal biopsy		✓										✓		

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Screening visit

If you decide that you want to be in this study, we will do some tests to see if you are able to enter the study. The screening visit will take about 1.5 hours.

- Your HIV infection status will be confirmed. If there is no record available, you will have another HIV test. You may have to sign a separate consent form before having this test.
- You will be asked about your health and medicines you have taken in the past or are taking now.
- You will have a complete physical exam including signs and symptoms, diagnoses, and vital signs (temperature, pulse, respiration rate, and blood pressure).
- If you are a woman able to become pregnant, you will be asked to give a urine sample to see if you are pregnant. You will not be able to enroll in this study if you are pregnant. You will be told the result of the test when it becomes available.
- You will have about 1 tablespoon or 15 mls. of blood drawn for CD4+ T-cell count and to measure HIV-1 viral load (the amount of virus in your blood), routine safety blood tests, and hepatitis screening (if information is not available within the past 6 months. You will be given the test results when they are available.
- The study staff will look at your veins to determine if you can have a special procedure to collect white blood cells during the pre-entry visit and one of your follow up visits.

Pre-Entry Visits

During these visits, you will have leukapheresis and rectal biopsy procedures done, which are described below. You will have blood drawn for safety tests, hematology, chemistry, CD4+ T-cell count, HIV-1 viral load measurement, samples stored for virology testing, and antibody testing and typing (about 1 tablespoon). You will also have blood stored for future tests (PBMC, leukapheresis). The visit is expected to last between 3 to 4 hours.

- Leukapheresis is a procedure in which the white blood cells are extracted from your blood. During this procedure, you will be asked to lie on a bed or reclining chair for the entire time, with a tube into a vein in each arm. One tube removes blood and passes it into a machine that removes white blood cells. The rest of your blood cells and normal blood fluid (plasma) go back into your body through the tube in your other arm. The treatment lowers the number of white blood cells immediately. This process will continue until all of your blood has been filtered up to 2½ times and will take about 2 hours. The total amount of blood taken from you for this procedure is equal to about 50 ml (3 tablespoons) of whole blood.

You will be monitored during and for 30 minutes after the leukapheresis and instructed to inform the medical staff immediately of any discomfort. Your body will make more white cells within a few days. Losing the amount of blood and the number of white blood cells that are collected does not pose a danger to you or to your health.

Aside from the placement of the needles, leukapheresis is not a painful procedure, but it may be uncomfortable to stay sitting or lying down in the same place for a long period of time.

Prior to the leukapheresis, you will have a pre-donor evaluation (PDE) performed at the Apheresis and Infusion Clinic on 3 Ravdin at the University of Pennsylvania. The purpose of the PDE is to assess your veins to make sure the procedure can be done, and to go over your medical history to determine if you have any contraindications to the leukapheresis procedure.

- A rectal biopsy is a procedure to remove a small piece(s) of rectal tissue for examination. The doctor uses a gloved, lubricated finger to check for abnormalities. Then, a lubricated instrument is placed into the rectum. You will feel some discomfort, a small sharp pinch, when this is done.

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During each biopsy procedure, about 12 tissue pieces will be collected. This procedure does not require anesthesia. The biopsy procedure takes approximately 30 minutes to complete.

On-study Visits

After your pre-entry visit, if you are still eligible, you will have to come to the clinic weekly. These visits will vary in length.

Infusion Visits (day 0 [entry visit], day 21, and day 42) - 3 hours

- During the entry visit, you will be asked about any illnesses that you have experienced within the past 30 days and a history of your medications (including start and stop dates).
- You will have a targeted physical exam, which will assess vital signs. At days 21 and 42, you will also be asked about any signs or symptoms that you have experienced since the last visit, and about any new medications that you have started or old medications that you have stopped since your last visit.
- If you are a woman able to become pregnant, you will be asked to give a urine sample to see if you are pregnant. If you are pregnant at day 0, you will not be able to proceed with the study. If you are pregnant after day 0, you will not be able to continue to receive VRC01, but can stay in the study.
- You will have about 6 tablespoons of blood drawn for routine safety blood tests, CD4+ T-cell count, viral load, along with other tests. In addition, some of your blood may be stored for future testing required by the study.
NOTE: You will not have blood drawn for CD4+ T-cell count on day 21.
- You will receive a dose of the VRC01 antibody.
- You will receive an infusion report card (IRC) to take home and use as a memory aid for side effects, on which you will record temperature and symptoms daily, for 7 days after infusion.
- You will continue on your normal ART regimen during the first dosing study week.
- You will have oral/rectal/cervical secretions collected. These samples will be collected after infusion of VRC01 and at day 63 and are described below.

For each secretion collection, the doctor or nurse will use a new sponge.

- Oral swab: The doctor or nurse will examine the inside of your mouth. If any problems are found, you may be referred for treatment. The treatment and any followup after treatment are not a part of the study. A doctor or nurse will insert a swab (like a long Q-tip) into your mouth and swabbed against your cheek. The sponge will absorb your fluid. This sample will be stored for future HIV related research. You will not receive the results of the test.
- Rectal swab: A doctor or nurse will insert a swab (like a long Q-tip) into your anus. The end of the swab will be rubbed against the skin inside the anus to absorb rectal fluids. This sample will be stored for future HIV related research. You will not receive the results of the test.
- Vaginal swab: Vaginal fluid secretions may be collected at the same visits as the rectal and oral samples, in eligible women. A doctor or nurse will insert a swab into your vagina. The end of the swab will be rubbed against the skin inside the vagina, to absorb vaginal fluids. This sample will be stored for future HIV related research. You will not receive the results of the test. This collection will not occur if you are having your menses.

Analytical Treatment Interruption (ATI) Visits

These visits will occur weekly beginning on day 7 and will stop once you have a confirmed viral load ≥ 1000 copies/mL or a confirmed decrease in CD4+ T-cell count below 350 cells/ μ L.

- You will have a targeted physical exam which will assess vital signs.

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- You will have 6 tablespoons of blood drawn for CD4 cell counts, HIV viral load, immune tests, along with other tests.(see table above). In addition, some of your blood may be stored for future testing required by the study.
- Study staff will collect your IRC on days 7, 28, and 49.
- On study day 7 you will discontinue your ART regimen.
 - You will restart ART when you have a confirmed viral load ≥ 1000 copies/mL or a confirmed CD4+ T-cell count < 350 cells/ μ L. We believe that the VRC01 infusions will keep your virus suppressed for the first 8 weeks – though this is not certain.
 - If you must restart before week 8, you will have the same evaluations that would have been done at the week 8 visit (with the exception of the leukapheresis, rectal biopsy, and some virology tests). You may have an additional study visit 4 weeks after your last VRC01 dose, to determine the drug exposure.
 If you have still not had a viral rebound by week 16, you will be strongly encouraged to resume taking your ART.
- On study day 63, you will have leukapheresis and rectal biopsy procedures done.
 - NOTE: Because you will have the leukapheresis procedure done on this day, you will have the equivalent of about 6 tablespoons of blood drawn during this visit. Some of your blood will be stored for future testing.

Confirmation of Viral Relapse (During ATI)

If you have a confirmed return of HIV viremia ≥ 1000 HIV RNA copies/mL or a confirmed CD4+ T-cell count < 350 cells/ μ L prior to day 63 (week 8 of the ATI), you will be asked to resume ART. If you begin taking ART before week 8, you will have to come in to the clinic for an additional visit. You will undergo the same evaluations as described for day 63 (week 8 of the ATI) visit, with the exception of leukapheresis and rectal biopsy.

ART Reinitiation

Evaluation	ART Restarted					Premature Discontinuation	Clinical Followup (As Needed)
	ART Reinitiation	Weeks					
		4	8	12	Q4*		
ART Restarted	X						
Clinical Assessments	X	X	X	X	X	X	X
Hematology	X	X	X	X	X	X	X
Chemistry & Liver Function Test	X	X	X	X	X	X	X
CD4+/CD8+	X	X	X	X	X	X	X
HIV-1 RNA	X	X	X	X	X	X	X

*Every 4 weeks until HIV-1 RNA < 50 copies/mL, after ART is reinitiated.

ART Reinitiation Visits (every 4 weeks until viral load < 50 copies/mL)

- You will have a targeted physical exam which will assess vital signs.
- You will have 2 tablespoons of blood drawn for routine safety blood tests, CD4+ T-cell count, viral load, immune tests, along with other tests. In addition, some of your blood may be stored for future testing required by the study.

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Genetic Testing

In the future, genetic research tests to help understand how VRC01 and methods of preventing HIV work may be done on your stored samples. Some genetic tests may be done to see if different types of immune responses to VRC01 are related to genetic differences in people. Genetic tests done in a research lab from your stored samples will not be in your medical record and will not have your name on the sample. The performance of these tests is not for health care purposes.

If You Have to Stop Taking the Study Drugs Early or You Have to Stop the Study Early

If you stop taking the study drugs or leave the study early after receiving VRC01, or prior to the completion of the VRC01 infusions, you will be asked to come to the clinic for an additional study visit. At this visit, you will have a targeted physical exam, which will assess vital signs, and have 1 tablespoon of blood drawn for routine safety blood tests, CD4+ T-cell count, viral load, immune tests, along with other tests. In addition, some of your blood may be stored for future testing required by the study.

If you stop taking the study drugs early, but wish to remain in the study, you will continue to come in for regularly scheduled study visits as outlined above. The only time that we will not collect samples from you when you have stopped taking VRC01 early is if you are pregnant or your study doctor determines it is not allowed according to the protocol.

During the study:

If you must permanently stop having VRC01 infusions before your study participation is over, the study staff will discuss other options that may be of benefit to you.

After the study:

After you have completed your study participation, the study will not be able to continue to provide you with VRC01 you received on the study, because its use in the general population is being studied.

If you do not enroll into the study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, sex, race), clinical (for example, disease condition, diagnosis), and laboratory (for example, CD4+ T-cell count [the number of white blood cells that fight infection], viral load) information is being collected from you so that ACTG researchers may help determine whether there are patterns or common reasons why people do not join a study.

Other

Some of your blood that is left over after all required study testing is done may be stored (with usual protectors of identity) and used for ACTG-approved HIV-related research.

STEP 3: Optional Evaluations

If you decide to continue with additional, optional testing for this research study, you will be asked to sign this consent form and have blood drawn for laboratory testing and two evaluations, leukapheresis and rectal biopsy, performed. These evaluations are similar to those performed in the previous steps of the study. These evaluations will help us understand the impact of the treatment interruption that occurred when you were taken off ART.

During the pre-entry visit, the study staff will document whether blood samples were taken on ART before you began study participation. You will have about 2 tablespoons of blood drawn for routine

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safety blood testing and to measure your HIV-1 viral load. The study staff will look at your veins to determine if you can have leukapheresis done. This visit is expected to last about 1 hour.

During the entry visit, you will have the leukapheresis and rectal biopsy procedures done, which are described below. The visit is expected to last between 3 to 4 hours. Sometimes, these procedures may be done on different days. You will be contacted by telephone, within a week of having these procedures, to answer questions about your health and any reactions to the procedures.

Why Would The Doctor Take Me Off This Study Early?

The study doctor may need to take you off the study early without your permission if:

- you do not receive any VRC01
- your study doctor or regular doctor thinks the study is no longer in your best interest
- continuing the study treatment may be harmful to you
- you are not able to take the study treatment as required by the study
- failure to attend study visits as required by the study
- your clinic site is no longer funded through the ACTG
- a Safety Monitoring Committee (SMC) recommends that the study be stopped early (an SMC is an independent group of experts who monitor the study)
- the study is cancelled by the sponsor, Principal Investigator, ACTG, institutional review board (IRB), Food and Drug Administration (FDA), NIAID, Office for Human Research Protections (OHRP), other government agency as part of their duties, investigator, or industry supporter
- you request to stop participating

The study doctor may also need to take you off the study drugs without your permission if:

- you become pregnant
- you have a bad reaction to the study drug
- you become ill and you do not get better before the next VRC01 infusion
- you are being treated with certain medications (the study staff will discuss these with you prior to giving you VRC01)
- you do not comply with the guidelines in this consent form
- if you take part in another study that issues study drugs that have not been FDA-approved, before receiving your last dose of VRC01.

If you must stop taking the study drugs before the study is over, the study doctor may ask you to continue to be part of the study and return for some study visits and procedures.

What Are The Risks Of The Study?

Risk of ATI

Discontinuing ART may result in viral rebound, where there are detectable levels of HIV in the blood after a period of undetectable levels. During this period of time, there will be levels of VRC01 antibody in your blood, but it is possible for your HIV virus to be resistant or become resistant to the antibody and the viral activity (viremia) reoccurs.. Discontinuing ART can also result in immune system stress. If your virus returns, your antiviral drugs will be restarted and you will be followed until your virus becomes undetectable.

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Risk of VRC01

VRC01 has not been tested in studies for preventing HIV transmission. There is some known safety information that has been collected from other studies using VCR01 in people, but these studies have not been completed. With antibody products, most side effects occur within the first 24 hours. This product may have a risk of serious allergic reactions. These reactions can be life-threatening.

- Anaphylaxis is one type of allergic reaction that may occur soon after an antibody product is given. It includes difficulty breathing, low blood pressure, hives or rash, swelling in the mouth and face.
- Serum sickness is a delayed type of allergic reaction that may occur several days to 3 weeks after an antibody product is given. It is characterized by hives or rash, fever, big lymph nodes, muscle pains, joint pains, chest discomfort and shortness of breath.
- You may also experience an increase in liver enzymes, which can be a sign of liver damage.

Antibody products for which serious allergic reactions have been observed are either targeted to attack a human protein or the antibody's structure is somewhat like an animal antibody. We expect that there will be a low risk of serious allergic reactions with VRC01 because VRC01 is a fully human antibody that attacks a virus. Some antibodies of the type that attack human proteins are known to increase the risk of serious infections. VRC01 is not expected to increase the risk of serious infections because, as noted above, it attacks a virus.

It is possible that VRC01 will have unknown effects on the course of your HIV infection, such as changes in CD4+ cell count and viral load levels, changes in ARV drug sensitivity, or other unknown effects. In addition to the possible risks that are listed above, VRC01 may have other side effects that we do not know about as yet. Participation in this study may limit your eligibility for other future monoclonal antibody studies.

We will give you any new information about risks or other information that becomes available that may affect your willingness to continue in the study.

In addition to the side effects listed above, other side effects may include: pain, headache, fever, nausea and vomiting, dizziness, trouble breathing, shortness of breath, tiredness, tightening of the muscles around the bronchial tubes, change in blood pressure (low/high), chills, diarrhea, itchiness, rash, hives, swelling (lip or face), increased heart rate or chest pain, fainting may occur after receiving the injection, which may result in falling with injury, shaking, stiffening, and other seizure-like activity have also been reported.

Risk of Blood Draw

Taking blood may cause some discomfort, bleeding, bruising, and/or swelling where the needle enters the body, and in rare cases it may result in fainting. There is a small risk of infection.

Risk of Rectal/Vaginal Swab:

Collecting the rectal and vaginal swabs may be an embarrassing experience, but should not be painful.

Risk of Leukapheresis

Side effects that can occur during leukapheresis include nausea, vomiting, fainting or dizziness, seizures, skin rash, hives, flushing (redness and warmth of the skin, usually the face), blood loss, and infection. Tingling of the lips, muscle cramping and, very rarely, changes in the heart rhythm can occur. These can be prevented or made milder by giving calcium supplements, either by mouth or in the vein, also called intravenous (IV). Very rarely, (less than 1 in 1,000 procedures), clotting may occur in the apheresis machine or in a patient and is potentially life-threatening. To reduce the risk of clotting, you will be given a drug called ACD (acid-citrate-dextrose). This drug may increase the risk of bleeding

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and may cause temporary tingling of the lips and limbs, muscle cramping, seizures, or changes in the heart rhythm. After the apheresis procedure you may experience temporary discomfort, including irritation, swelling or bruising at the place where the needle was inserted into your vein to collect the blood. Other risks from leukapheresis are similar to those from a blood draw as described above.

Risk of Rectal Biopsy

Removing the rectal tissue may cause some discomfort and bleeding (which could last for 2-3 days). There is a small risk of infection. Infection and/or bowel perforation are extremely rare complications that may require antibiotics and/or surgical repair. Participants will be followed in clinic as well as the surgical clinic for any complications.

Risks of Social Harm

Although the study site will make every effort to protect your privacy and confidentiality, it is possible that your involvement in the study as a participant could become known to others if it is not already and that social harms may result (because you could become labeled as being infected with HIV). For example, you could be treated unfairly or discriminated against by family members, friends, and/or the community.

Are there Risks Related to Pregnancy?

VRC01 is not approved for use in pregnant women. If you are having sex that could lead to pregnancy, you must agree not to become pregnant during the treatment period. There are several different birth control methods to prevent pregnancy available to you at your clinic.

- Male condoms with spermicide
- Nonhormonal IUDs, such as ParaGard
- Tubal ligation
- Vasectomy
- Complete Abstinence, which means complete avoidance of heterosexual intercourse and is an acceptable form of contraception for all study drugs. If you choose this method, you are not required to use a second method of contraception, but if you are female, you must continue to have pregnancy tests.

NOTE: Female participants and male partners must use the forms of birth control throughout the study and for a total of 14 weeks after receiving the last dose of VRC01.

Female partners of reproductive potential of male study participants must agree to use two forms of birth control, including:

- Male condoms with spermicide
- Hormonal methods for birth control, including combined oral birth control pills, vaginal ring, injectables, implants, and intrauterine devices (IUDs), such as Mirena, since they will not be receiving study drug.
- Nonhormonal IUDs, such as ParaGard
- Tubal ligation
- Complete Abstinence

NOTE: Male participants and female partners must use the forms of birth control throughout the study and for a total of 23 weeks after receiving the last dose of VRC01.

If you are interested in starting a form of birth control, please talk with study staff about how you can obtain your desired choice of birth control.

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All female participants must have a pregnancy test before each dose of VRC01. The test must show that you are not pregnant in order for you to participate in the study. If you think that you may be pregnant later in the study (after all VRC01 have been given), you should tell your provider or study staff.

If you become pregnant after receiving VRC01, site staff will request to contact you regarding your pregnancy. We will collect information about you and about the outcome of your pregnancy (even if your participation in the study has ended).

If you are taking anti-HIV drugs when you become pregnant, your pregnancy will be reported to an international database that collects information about pregnancies in women taking anti-HIV drugs. This report will not use your name or other information that could be used to identify you.

Are There Benefits to Taking Part in This Study?

If you take part in this study, it is unlikely that it will benefit you directly. The information learned from this study may help others who have HIV.

Will I Receive the Results of Any Tests?

You will receive the results of routine lab tests (eg, blood counts, liver and kidney tests) that are performed at the study visits. You will be told of any new information learned during the course of the study that might cause you to change your mind about staying in the study. At the end of the study, you will be told when study results may be available and how to learn about them. As with all studies, if we find out important information that may affect your care, you will be provided with those results.

What Other Choices Do I Have Besides This Study?

You can choose not to be in this study, continue with your normal medication regimen, and be followed routinely by your regular doctor or health care provider.

Please talk to your doctor about this and other choices available to you. Your doctor will explain the risks and benefits of these choices.

What About Confidentiality?

We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have obtained a Certificate of Confidentiality from the U.S. Federal Government. This certificate means that researchers cannot be forced to tell people who are not connected with this study, such as the court system, about your participation. Also, any publication of this study will not use your name or identify you personally.

People who may review your records include the ACTG, Office for Human Research Protections (OHRP) or other government agencies as part of their duties, Food and Drug Administration (FDA), the University of Pennsylvania institutional review board (IRB), National Institutes of Health (NIH), study staff, study monitors, drug companies supporting this study, other government agencies and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

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

Your personal information may be given out if required by law. If you test positive for HIV or if a CD4 or HIV viral load is done at a study visit, by law we have to report the result to the City of Philadelphia Health Department/PA Department of Health. 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.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What personal health information is collected and used in this study and might also be disclosed?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, email address
- Dates directly related to you such as date of birth and clinic visits.
- Personal and family medical history
- Current and past medications or therapies
- Questionnaires
- Results of tests and procedures you will undergo during this research
- Social Security Number, Medical record number

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

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As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

- ACTG Data Coordinating Center, Frontier Science Technology Research Foundation (FSTRF): Data for this study will be recorded on case report forms, keyed into a central database and electronically submitted to the Data Coordinating Center. The data will be cleaned and stored at this facility until it is ready to be analyzed.
- Statistical Data Analysis Center (SDAC): Approved data will be downloaded from FSTRF to the statistical data center for the AACTG at the Harvard School of Public Health. Specific study reports will be periodically provided to the study team and data safety review board to monitor if the trial is safe.
- Pharmaceutical sponsor (Vaccine Research Center (VRC)) The company that is supplying the monoclonal antibody for this study
- Contract Research Organization (PPD, Inc): Monitors from PPD will visit the AACTG on a quarterly basis to review data and correct mistakes before the data are sent to SDAC for analysis.
- Government Agencies: Data from this study will be made available to the National Institutes of Health/Division of AIDS (DAIDS)/National Institute for Allergy and Infectious Disease (NIAID), for them to evaluate the safety and efficacy of the treatments being used in this study.

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- Food and Drug Administration

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study drug you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

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

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You must do so in writing to the Principal Investigator at Infectious Disease Division, 502

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Johnson Pavilion Philadelphia PA 19104. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study. You will also be given the UPHS and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your personal health information.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What Are the Costs To Me?

There will be no cost to you for any of the tests that you have as part of this study. Taking part in this study may lead to added costs to you and your insurance company. In some cases it is possible that your insurance company will not pay for these costs because you are taking part in a research study.

Will I Receive Any Payment?

You will be compensated \$50 for each required study visit you attend; with the exception of the visits noted below that have alternative compensation amounts. Visits with total compensation amounts above \$100 will be in the form of a check. This check will be mailed to you in about 4 to 6 weeks after your visit.

Leukapheresis visits (pre-entry and week 9, Step 3 optional evaluation) \$150

Rectal biopsy: (pre-entry and week 9, Step 3 optional evaluation) \$100

VRC001 infusion: (entry, week 3, week6) \$75

Oral/vaginal/rectal swabs: (entry, week3, week 6, week 9): \$25

The total compensation for the study will vary from participant to participant as some visits will occur only when certain points are met in the protocol.

There is no other form of compensation available such as reimbursements for parking, tokens or child care. In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of \$600 in a calendar year.

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What Happens If I Am Injured?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or the National Institutes of Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

What Are My Rights As a Research Subject?

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. Your healthcare provider will treat you the same no matter what you decide.

We will tell you about new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know.

What Do I Do If I Have Questions Or Problems?

If you have questions about this study or a research-related injury, please contact the research team listed on page 1 of this consent form.

For questions about your rights as a research subject, contact:

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

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CONSENT

On page 5 of this consent form you were informed about optional tests to be done on your leftover blood.

If you agree, any blood left over after all required study testing is done may be stored (with no information that will identify you) and used for future ACTG-approved research. These blood samples may be stored for an unknown period of time. Results of testing done on these samples may not be given to you because they will be done in the future.

Please tick the box below to indicate your choice. You may change your mind at any time and reasonable efforts will be made to destroy your samples, though this may not always be possible.

- ☐ I agree to allow additional testing performed my extra samples for future ACTG-approved research
- ☐ I do not allow my extra samples to be used in future research

If you agree to take part in the optional evaluations to be conducted under STEP 3 described on page 6 of this consent form, please sign your name below.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

Name of Subject (Please Print)

Signature of Subject

Date

Name of Person Obtaining
Consent (Please Print)

Signature

Date