RV 584 INFORMED CONSENT FORM

STUDY TITLE: Phase 1b Single Dose Clinical Trial of a Novel Long-Acting Bispecific Antibody in People with HIV to Inform Development for HIV Pre- and Post-Exposure Prophylaxis

SPONSOR: David D. Ho, M.D.
Director, Aaron Diamond AIDS Research Center
Clyde and Helen Wu Professor of Medicine
Director, Wu Family China Center
Columbia University Vagelos College of Physicians and Surgeons
New York, NY

FUNDING SOURCE: U.S. Military HIV Research Program (MHRP)

STUDY AGENTS PROVIDED BY: David D. Ho, M.D., Columbia University Vagelos College of Physicians and Surgeons, New York, NY, USA and the National Institutes of Health (NIH), Bethesda, MD, USA

STUDY SITE: National Institute for Medical Research-Mbeya Medical Research Centre (NIMR-MMRC), Mbeya, Tanzania

PRINCIPAL INVESTIGATOR: Marco Missanga, MD, MMed

IND NUMBER: 141672

Study Contacts Information

Principal Investigator: Marco Missanga, MD, MMed
Mobile: +255 713 338 644
Phone: +255-25-250-6164
E-mail: mmissanga@nimr-mmrc.org

Study Coordinator: Wiston William, MD, MSc
Mobile: +255 768 685 076
Phone: +255-25-250-6164
Email: wwilliam@nimr-mmrc.org

Introduction

Thank you for your interest in this research study. This study will take place at the National Institute for Medical Research-Mbeya Medical Research Centre (NIMR-MMRC), Mbeya, Tanzania.

This study is supported by the United States Department of Defense (U.S. DoD). The box below titled 'Key Information,' provides important information about the study that you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will offer you a signed copy of this form to keep. If you have any questions during any part of the study, you may contact the Principal Investigator or study coordinator, whose contact information is listed above.

Key Information	
Voluntary Participation	You are being asked to volunteer for a research study. You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled.
Purpose	We are doing this research to test how safe and well-tolerated the investigational drug (called 10E8.4/iMab) alone and when combined with another investigational drug (called VRC07-523LS) in people living with HIV. We are also evaluating how these drugs alone and in combination will reduce the amount of HIV in your body.
Duration	We will screen you to evaluate if you meet the criteria to join this study. This visit may take up to 3 hours. If you are found to be eligible, you will then be considered enrolled into the study and have a maximum of 11 study visits. These will take place at various time points over the course of up to 50 weeks, or 11.5 months. Most participants will only have to come in for 10 study visits, unless there is a special circumstance. There is a Visit Schedule we will review with you to show you the specific timing of each visit and the study team will work with you to schedule your visits at a time that is convenient for you. Most visits should take approximately 1-2 hours. If you are assigned to one of the study groups receiving the investigational study drug(s), the first study visit will be longer and will take approximately 3-4 hours.

Procedures	Once you are enrolled into the study, the study will be divided into two parts: 'Step 1' and 'Step 2.' The primary purpose of Step 1 is to see how your body responds to a single dose of the investigational drug called 10E8.4/iMab alone or in combination with the investigational drug called VRC07-523LS. In Step 1, you will be assigned to one of five study groups. Each group will have four participants. Depending on the group to which you are assigned, you will receive either standard daily oral medications for HIV, 10E8.4/iMab alone, or a combination of 10E8.4/iMab and VRC07-523LS. Depending on the study group, you may receive 10E8.4/iMab either through a catheter in your vein or through injections into your muscle. You will have a total of 5 study visits as part of Step 1 over the course of 2 weeks. During Step 1, your HIV levels (viral load) and any potential side effects that you may experience will be monitored. Once Step 1 ends, you will move to Step 2 of the study and will start receiving standard daily oral ART (or if you are part of the study group assigned to ART in Step 1, you will continue on your ART regimen) according to the local standard of care procedures at your study site. ART is not provided as part of the study but will be coordinated through the study site. You will have a maximum of 6 visits in Step 2 over the course of 48 weeks, but most participants will only have 5 visits. The purpose of Step 2 will be to see if the study drug(s) administered in Step 1 had any effect on the amount of HIV in your body and to monitor any side-effects you may feel for safety purposes. During Step 2, your HIV levels (viral load) be monitored at every visit until the final visit. Other procedures during the study include: o Discussion about your medical history o Collection of blood and urine samples for laboratory testing and pregnancy testing (for women of childbearing potential) o Physical examination and vital sign collection o Recording of any side effects you may experience o Optional collection of samples from the vagina, penis, or rectum o Optional collection of spinal fluid

Risks	Most studies have some possible harms that could happen to you if you join. In this study, there may be risks associated with the I.V infusions, the study drugs, the blood draws, privacy, and the optional procedures. These risks are outlined in detail in this consent form below. The most serious risk is the possibility of a severe allergic reaction.
Benefits	This study is experimental and you should expect no direct benefit from participating. However, the knowledge gained from his study may be helpful to inform development of drugs to prevent or treat HIV in the future and benefit society. As part of the study procedures, you will have laboratory testing done and you may have some benefit from the identification of any infections or other medical conditions.
Alternatives	Participating in this study is voluntary and the alternative is to not participate. If you are living with HIV and are not on medications to treat HIV when deciding whether to join the study, you may choose to start medications to treat HIV immediately instead of participating in the study.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this study because you are an adult living with HIV and have never received medications to treat HIV, called antiretroviral therapy (ART), or have not been on ART in the last 24 weeks.

We are doing this research to test how safe and well-tolerated the investigational drugs (called 10E8.4/iMab and VRC07-523LS) are alone at different doses, when given by an infusion into your vein (intravenously), when given as an injection into your muscle, and when combined together in people living with HIV. We are also evaluating how effective these drugs are at reducing the amount of HIV in your body, both alone and when combined together.

10E8.4/iMab and VRC07-523LS are part of a drug group called monoclonal antibodies (mAbs). Antibodies are substances your body makes to fight infections in your blood. These antibodies target the HIV virus. These antibodies were not made by collecting them directly from a person. They were made in a lab that is designed for drug manufacturing under controlled, clean conditions.

In research studies that test other mAbs, the use of multiple types of mAbs at the same time has shown better results than the use of a single mAb. As a result, we are testing both drugs (10E8.4/iMab and VRC07-523LS) in this research study to see if this combination is more effective at reducing the amount of HIV in your blood (viral load). This information will help researchers understand how these drugs might be useful for preventing or treating HIV in the future.

The safety of each of the study drugs has been tested previously in human research studies. The combination of both together has never been studied in humans before, and, as a result, not all of the side effects are known.

The study drugs are investigational, which means they have not been approved or cleared by the U.S. Food & Drug Administration (FDA) or the Tanzania Medicines and Medical Devices Authority (TMDA) for treating HIV. However, these authorities have allowed the use of these drugs in this research study to learn more about their safety and ability to treat HIV.

WHERE WILL THIS STUDY TAKE PLACE?

This study will take place at the NIMR-Mbeya Medical Research Centre (MMRC), Mbeya, Tanzania.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Up to 20 total participants will participate in this trial, with 4 participants in each study group.

HOW DO I JOIN THIS STUDY?

If you decide to take part in this study, you will sign this consent form to indicate that you are aware of the procedures you will undergo, the risks, and all other implications of joining this study and agree to participate. After signing the consent form, you will have a screening visit.

During the screening visit, you will be asked to take a test of understanding to see how much you understand about the study and the information provided to you here. You must answer at least 9 out of 10 questions correctly to participate in the study. You may take the test up to 3 times to get a score of 9 out of 10.

You will also have blood collected for lab tests, urine collected for lab tests, and may have oropharyngeal (back of throat) or rectal swabs collected (if deemed appropriate by the study investigator). You will have a review of your medical history, medication history and demographic information. The study team may need to access your HIV records to confirm your eligibility for the study. You will also be asked questions of sensitive nature; such as your alcohol use and injected or other recreational drug use.

A physical examination including vital signs will also be performed. The purpose of the information and samples collected during screening is to ensure you are eligible to participate in the study.

The tests that will be performed on the blood samples collected are tests to check your HIV status and tests for sexually transmitted infections (STIs) such as: hepatitis B, hepatitis C, syphilis.

Additional tests will be performed to evaluate the levels of different types of cells in your blood; and tests to see if your liver and kidneys are functioning normally. The tests that will be performed on the urine samples will be used to check your pregnancy status (for females who are able to bear children), and to diagnose urinary tract infection and other STIs such as: gonorrhea and chlamydia.

After your test results are available, the researchers will review the results to determine if you meet the requirements to enroll in this study (in other words, if you are eligible to participate). If study researchers identify any health findings that may require further evaluation or treatment, they will help you (as applicable) and ensure that you receive appropriate care.

If you are eligible and want to enroll in the study, the study staff will work with you to schedule your next study visit and all future follow-up visits. If you are not eligible, you will not be asked to return for any additional visits and will not be enrolled in the study. Samples and data collected from you during your screening visit may still be used and evaluated as part of the study even if you are not eligible to participate in additional visits.

You may be allowed to participate in this study if you meet all the following criteria:

- Are able to read and write in Kiswahili and/or English
- Have provided your consent by signing this consent form
- Have successfully answered the Test of Understanding (TOU)
- Are 18-50 years old
- Weigh between 50kg and 100kg
- Are a person living with HIV
- Have never been on ART or have not received it for at least 24 weeks
- Are willing and able to participate in the study for up to 50 weeks
- Are willing and able to start ART as directed during the study
- Are willing to use a barrier protection (like condoms) when having sex with partners without HIV or with unknown HIV status throughout Step 1 of the study and until your viral load reaches a target amount in Step 2 (the study team will help communicate this to you)
- Are willing to meet requirements to prevent pregnancy:
    - If you participate in sexual activity that could lead to you becoming pregnant, you must be using at least one highly effective method to prevent pregnancy at time of screening. This must have started at least 14 days prior to study enrollment and continue for 25 weeks (approximately 6 months) after receiving the study drug(s):
        - Contraceptive implant
        - Intrauterine device (IUD)
        - Oral birth control pills
        - Injectable birth control
        - Vaginal ring
        - Birth control patch
        - Tubal ligation (surgical procedure to tie off fallopian tube)

If you participate in sexual activity that could lead to your sexual partner becoming pregnant, use a barrier method (like condoms) during the study.

You will not be allowed to participate in this study if you:

- Have received a drug similar to the product we are investigating or are receiving a drug that affects your immune response
- Have a history of failed treatment on two or more ART regimens
- Have a planned or anticipated need for enfuvirtide, maraviroc, fostemsavir, or ibalizumab for ART
- Have an AIDS-defining illness
- Have ongoing oral thrush
- Have used injection or recreational drugs in the past 12 months, that, in the opinion of the investigator would affect your ability to be part of the study
- Have a history of severe allergic reaction in the past 2 years
- Have a history of chronic hives that require daily treatment
- Have untreated syphilis
- Have active hepatitis B, active hepatitis C or have had one of these in the past
- Have abnormal laboratory values (investigators will determine this based on laboratory tests performed at your screening visit)
- Are pregnant or breastfeeding
- Have received any vaccine or an investigational drug in the past 28 days or have ever participated in an HIV vaccine study
- Are participating or are planning to participate in another clinical trial during the study period
- Chronic or recurrent use of medications that modify your immune response, such as oral steroids, IV steroids, or cancer chemotherapy
- Have a medical condition or are taking medication that prevent you from safely participating, in the opinion of the investigators

WHAT WILL HAPPEN DURING THE STUDY?

After you complete your screening visit today and are found eligible to participate in this study, you will be considered enrolled in the study. You will then be scheduled for your first study visit and will be assigned to one of five study groups as listed below:

- Group 1: Standard daily oral ART- which is the standard of care treatment of HIV
- Group 2: A single dose of 600mg of 10E8.4/iMab, administered intravenously (directly into the vein)
- Group 3: A single dose of 600mg of 10E8.4/iMab, administered intramuscularly (into your butt muscle)
- Group 4: A single dose of 1800mg of 10E8.4/iMab, administered intravenously (directly into the vein)
- Group 5: A combination of 1800mg of 10E8.4/iMab and 1200mg VRC07-523LS, administered intravenously (directly into the vein)

The study drug(s), should you be assigned to a group that receives them, will be administered at your first study visit (Visit 1). The first 5 study visits will occur over the course of 2 weeks. This part of the study will be referred to as "Step 1." In rare circumstances, some participants may have less than 5 study visits as part of Step 1 if the investigator decides to move you to the next step early to ensure your safety or for any other reason.

Following Step 1, you will be asked to come in for a maximum of 6 more study visits, although most participants will only have 5 more study visits. This part of the study will be referred to as "Step 2." If you were assigned to Groups 2 through 5 then during Step 2 of the study, you will begin to receive daily ART, the standard of care treatment of HIV. You will also be asked to come in so the study team may see if the study drug(s) you received in Step 1 were effective in reducing your viral load. If you were assigned to Group 1, you will continue to receive standard daily ART during Step 2 of the study. For most participants, Step 2 will occur over the course of approximately 48 weeks.

The Step 1 portion of the study will be dedicated to monitoring the levels of HIV in your body to make sure they are within a safe range and to see how the study drug (or study combination) is affecting you. In Step 2 of the study, you will begin (or continue, if you are in Group 1) treatment with standard daily oral ART, which you will receive at your local study site.

You will also have the following procedures performed during study visits:

- The study team will perform a physical examination and take your vital signs.
- The study team will ask for any updates on medical events or medications since your screening visit.
- You will have a blood draw at every study visit for the purpose of this research. The blood we collect will be used to see how the study product is working in your body. The amount of blood you will have drawn in a single day while on this study will vary between 19 mls (or approximately 1.3 tablespoons) and 132.5mls (or approximately 9 tablespoons) depending on the study visit. Over the course of the study, you will have approximately 816.5mls of blood drawn (or approximately 55 tablespoons).
- If you are capable of bearing children, you will be asked to provide samples of your urine over the course of the study for pregnancy testing.

The exact study procedures will vary by study visit. Details of what will occur each day you are on study will be broken down in the Participant Visit Schedule which you will be reviewed with you alongside this consent, and during your study visits.

If you choose to take part in this study, we will ask you to sign this consent form before we do any screening tests or study procedures.

Optional Procedures

An optional mucosal secretion collection (collection of samples from the vagina, penis, and/or rectum) may be performed if you agree to undergo this additional procedure. Further information regarding the mucosal secretion collection can be found in the separate Optional Procedures Informed Consent Form (ICF).

An optional lumbar puncture (spinal fluid collection) may be performed if you agree to undergo this additional procedure. Further information regarding the lumbar puncture can be found in the separate Optional Procedures ICF.

You do not need to agree to these procedures to participate in this study.

WHAT ARE MY RESPONSIBILITIES DURING THIS STUDY?

If you take part in this study, you will be asked to:

- Provide complete and accurate information about your medical history, medication use, and any symptoms or illnesses you have during the study.
- Follow the study staff's instructions and complete your diary card. You will be asked to complete a diary card to record any symptoms/reactions you may experience starting the evening you received the study drug(s) and then for 7 additional days.
- Attend all study appointments and be available for telephone calls from the study staff. If you cannot keep an appointment, contact the study clinic immediately to reschedule.
- Follow the barrier method and contraception requirements listed above under the '*You may be allowed to participate in this study if you*' section. Please inform the study doctor/staff immediately if you do become pregnant during the study.
- Inform the study doctor/staff of any change in your health status, side effects, visits to another doctor/hospital and any changes in your plans or ability to participate in the study.
- Not enroll in ANY other clinical research study while you are in this study.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Risks Associated with 10E8.4/iMab:

The first in human trial with 10E8.4/iMab completed the dosing of participants and all follow-up in July 2021 and final analyses of the results are nearly complete as of February 2023. During the this study, a total of 48 clinical trial participants received the 10E8.4/iMab investigational drug. Of these 48 participants, 39 were not living with HIV and 9 were living with HIV. The participants not living with HIV received a single dose of this drug in a variety of methods (injected directly into the vein and into the fatty tissue under the skin) and at different doses (0.3mg/kg, 1mg/kg, 2.5mg/kg, 10mg/kg, and 30mg/kg). The participants living with HIV received a single dose of 10E8.4/iMab at either the 10mg/kg or the 30mg/kg dosage intravenously.

Some participants taking this drug in this trial experienced the following:

- Unpleasant taste
- The accumulation of fluid in the lower legs
- Formation of a lump at the injection/infusion site
- Pain at injection/infusion site
- Tenderness at injection/infusion site
- Reddening of the skin
- Swelling at injection/infusion site
- Bruising at injection/infusion site
- Itching at infusion/injection site
- Sensation of warmth

- Tiredness
- Itching
- Rash
- Headache
- Muscle aches and muscle pain

There may be other side effects to this product that we do not know about yet. We will continue to update you as more is learned about 10E8.4/iMab.

Risks Associated with VRC07-523LS:

As of December 2023, VRC07-523LS has been administered to approximately 898 adults not living with HIV, 153 adults living with HIV, and 38 infants exposed to HIV across 24 clinical trials (15 completed and 9 ongoing with preliminary data). Participants took VRC07-523LS both in combination with other drugs and alone.

Some participants taking this drug in clinical trials experienced the following:

- Muscle pain
- Headaches
- Chills
- Diarrhea
- Pain
- Tiredness
- Chest tightness
- Shortness of breath
- Difficulty breathing
- Wheezing
- Low blood pressure
- Rash
- Hives
- Swelling
- Itching
- Vomiting
- Temporary changes in liver enzymes/proteins

Risks Associated with the Combination of 10E8.4/iMab and VRC07-523LS:

10E8.4/iMab and VRC07-523LS have not been studied together in humans before and therefore, we do not yet know the risks of taking these drugs in combination. However, these drugs have been studied separately in human beings before and similar drugs have safely been delivered in combination in the past.

Risks Related to Infusion and/or Injections:

Risks of infusion with drugs like 10E8.4/iMab and VRC07-523LS include pain, tenderness, warmth, itching at the infusion/injection site, reddening of the skin, development of a lump, and bruising. There is a rare possibility of an "infusion reaction" which may cause: fevers, chills, nausea, sweating, shortness of breath, and possible low blood pressure.

Procedures to manage potential reactions from study drugs and infusions/injections:

The study staff are trained to take the right measures to reduce risks and limit any discomforts you may experience. If you are in Groups 2-5 and receive a study drug(s) (10E8.4/iMab and/or VRC07-523LS), you will be monitored for at least 45 minutes at the study clinic for safety monitoring. A study clinician will assess you before you leave, and also during scheduled follow-up visits. These reactions will be closely monitored, but are generally short-term and resolve on their own, without requiring treatment. The study clinic has emergency medical equipment in place to handle any allergic reactions if they should occur. You will also be asked to record any symptoms/reactions you may experience on the study diary card, which you will bring with you back to the study clinic to share with the study team. You may contact the study team using the contact information in this consent form, if you have any questions about any symptoms/reactions you experience at home.

Risks Related to Blood Draw:

Blood draws may cause pain and bruising and may, infrequently, cause a feeling of lightheadedness or fainting. Rarely, it may cause infection at the site where the blood is taken. To minimize the risks, trained health care providers will draw your blood.

Risks related to Pregnancy and Breastfeeding:

We do not know the possible effects of the study drugs on the fetus or nursing infant.

If you are pregnant or breast-feeding, then you will not be eligible to participate in this study. We will test for pregnancy before enrollment into the study and at follow-up visits. Participants who have the ability to become pregnant must use effective birth control methods 14 days prior to starting and until the trial is complete. You must tell the study doctor or a member of the study

team if your birth control method fails or if you think you have become pregnant while participating in this research study. If you do become pregnant, the study team will continue to follow you to term and ask you questions about your pregnancy and the birth. Participants who have the ability to get their partner pregnant must use a barrier method at the start of the study and until the trial is complete.

Risks related to Genetic Testing:

The greatest risk associated with genetic testing is your privacy. Genetic test results can be used to provide information about how susceptible you are to certain diseases. Used inappropriately, this information could be discriminatory (for example, by insurance companies). The risk of this happening is extremely low, because your results will not be part of your study records and will not be provided to the clinic. HLA typing can also be used to figure out who the true parent of a child is (if compared to the child's HLA type). However, the blood samples that you donate will not be used for this purpose; they will be used only to provide study investigators information about your immune system. All results will only be labeled with your study number and won't contain personal information to protect your identity. Neither you nor your doctor will get the results as the tests are for research purposes only and not used to make health-related decisions.

Risks Related to Positive Test Results

If you are being screened for this study, you are likely to be a person living with HIV and are already aware of your HIV status. HIV testing is performed as part of the screening procedures for this study to confirm your HIV status and confirm that you are eligible to participate (you must be living with HIV to be eligible). It is rare, but possible that you could find out that you are a person living with HIV during the screening process. Finding out your HIV status could result in emotional feelings or distress, depression, and rarely, suicide. The study team will help counsel you and provide you with support.

As part of this study, you could also become aware of a positive test result for other STIs (such as hepatitis B, hepatitis C, syphilis, gonorrhea, or chlamydia). This could also result in negative emotional feelings or distress. STIs are treatable diseases. The study team will help counsel you and will help refer you to care and treatment, as needed.

Risks Related to Possible Breach of Confidentiality and Social Risks:

The study team will take all possible steps to protect your privacy and maintain confidentiality throughout your study participation. This includes keeping any test results confidential to minimize the risk of stigma from others finding out about your health status. Although the risk is low due to the confidentiality measures taken by the study team, it is possible that your friends, family, or others could potentially find out about your participation in the study. You may be

treated unfairly because family, friends, co-workers, employers, the community, or others learn you are in this study and learn that you are living with HIV. This could result in stigmatization in your community and problems with your employment, insurance, depression, and, rarely, suicide. Your STI results will also be kept confidential and the risk of having your STI status revealed to others is low. If others learn you have an STI, you could be treated or judged unfairly in your community. Study staff will take appropriate action to assist you with any discrimination you may experience by being in this study. Such measures will be accompanied by appropriate counseling and treatment.

Additionally, as part of the screening procedure for this study, we will ask sensitive questions about your alcohol and drug use. These questions may make you feel uncomfortable.

To further minimize these risks, the study team will conduct all study visits in private rooms where you won't be seen or heard from the outside. Study documents will use codes to identify you and your samples and will not include any personal information that would identify you. All paper study documents will be stored in locked cabinets in the clinic with limited access by study staff.

If you encounter any confidentiality or social issues while in the study, please talk to the study staff so they can help you.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

This study is experimental and you should expect no direct benefit from participation in this study. However, the knowledge gained from this study may inform development of drugs to prevent or treat HIV in the future. This research has the potential to benefit society and guide future research related to HIV prevention and treatment. As part of the study procedures, you will have laboratory testing done and you may have some benefit from the identification of any infections or other medical conditions.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Participating in this study is voluntary and the alternative is to not participate. If you are living with HIV and are not on ART when deciding to join the study, you may choose to start ART immediately instead of participating in the study.

WHAT IF THE RESEARCHERS LEARN NEW INFORMATION DURING THE STUDY?

During the course of the study, you will be informed of any significant new information or findings (either good or bad), such as changes in the risks or benefits resulting from participation in this trial or new alternatives to participation that may affect your health and willingness to continue participation. We may contact you after the study ends if we have other information related to this research that is relevant to you.

WHY MIGHT RESEARCHERS ASK ME TO LEAVE THE STUDY EARLY?

Researchers may ask you to leave the study if the sponsor ends the study early or cancels the study. This could be due to, but is not limited to, funding reasons or safety reasons. The medical staff could also decide it is not good for your health to continue participating in the study. Researchers may ask you to leave for failure to comply with protocol requirements.

WHAT WILL HAPPEN TO MY SAMPLES AND DATA?

The study team will take blood samples from you to assess your health and for research purposes throughout your study participation. Your samples will be analyzed at approved laboratories in Tanzania, the United States, and Thailand. All of your identifiers, such as your name, date of birth, address, etc. will be removed and only labeled by a code so you will not be identified directly. This is to help them learn more about the products that are being studied and to understand how they work within your body. This includes how they affect HIV, your immune system, and your health. Clinical information that may be beneficial to your health will be shared with you and the team will help link you to any additional medical care, as applicable for any conditions identified during your participation. Your results testing that is done only for research purposes will not be shared with you.

Some of your blood will be used to check for hepatitis B, hepatitis C, HIV, and other sexually transmitted infections. Genetic testing may also be conducted on your samples during this study. For example, researchers may do “genetic variations” research. They may look at genes that affect how you fight infections. Your genes are passed to you from your birth parents. Genes are the basic “instruction book” for the cells that make up our bodies. The differences in people’s genes can help explain why some people get a disease while others do not. The genetic research tests we plan to conduct are not currently used in medical practice. The results of such tests have not been approved for use in making health care decisions and the results will not be shared with you. To protect your identity, your genetic testing results will not be linked to your name and will not independently identify you as an individual. The research for this study will not include mapping of all your genes (called “whole genome sequencing”).

Documents, (including this form) notes from your visits, and photographs, if any, will be stored securely and then destroyed by authorized individuals when these records are no longer needed.

The study team will make their best effort to share the overall results and findings from this study with you once available. It could take several months to one year after your participation ends to have these study results available. Your specimens (which won’t include identifying information) may be used for commercial profit, however you will not share in this commercial profit.

Future use of your samples and data in other research studies

You have the option to allow your coded samples and data that were collected as part of this study to be used for studies other than the one described in this consent form. You also have the option to allow or decline genetic testing to be performed as part of this future research. These studies may provide additional information that will be helpful in understanding HIV, other infectious diseases, and related conditions. These studies may be going on now, at any point during this study, or after the study is completed. All of your identifiers, such as your name, date of birth, address, etc. will be removed and only labeled by a code so you will not be identified directly. The researchers of this study do maintain the code key to your identity, but it is kept confidential and would not be shared with other researchers.

If you consent to the future use of your samples and data, we may share study information and or samples to other research collaborators outside of WRAIR, MHRP, and the other institutions listed in this consent form without asking for your permission and there is no time limit on how long your data and samples will be stored for future use. All future research that uses stored data and samples must also be reviewed and approved by the responsible organizations and their institutional review boards (IRBs).

You will make your choice about future use at the end of this consent form, prior to signing. Your choice will not affect your participation in this study and you can still participate if you decline the future use of your samples and data.

If you agree now and decide later during your study participation that you do not want us to use your data and samples for future research outside of this study, please let the study team know. You can change your mind about this any time during your study participation. If you change your mind, we will do our best to comply with your request but cannot guarantee that we will always be able to destroy coded specimens and data that have already been collected. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

How long will your specimens and data be stored?

At the end of the study, your data will be stored securely for a minimum of 5 years and will then be destroyed as per applicable regulations. At the end of the study, your remaining specimens will be destroyed as per applicable regulations.

However, if you consent to the future use of your data and specimens (as described above), both your data and specimens will continue to be securely stored for an unknown period of time to allow for their use in future, IRB-approved research. Protections for privacy and confidentiality described in this document will apply to any future use of your stored data and samples.

WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw from this study at any time. If you choose to leave the study, data collected prior to your withdrawal will remain in the research database and will be included in data analysis. Your stored samples will only remain available for future IRB-approved research if you have consented to the storage and future use of your samples (as indicated by your choice at the end of this consent form).

You may withdraw your consent at any time and stop participating in this research study. Leaving the study will not impact your ability to receive care or any other benefits that you would have received otherwise. Should you choose to withdraw, you should inform the study team of your decision.

WILL I RECEIVE ANY PAYMENT FOR MY PARTICIPATION IN THIS STUDY?

Participants will be compensated 25,000 TZS per visit for their time, income lost while attending study procedures, and any cost or inconvenience related to study participation. If your study related costs are more than the specified amount and you have proof of such costs, please discuss it with your study doctor. You may also receive additional compensation if you consent to and have any of the optional procedures performed. Those amounts are specified in the separate Optional Procedures ICF.

Payments will be made at the end of each visit and will not be provided in advance, nor held until the end of the study.

Other than medical care that may be provided and the compensation stated above, there is no other payment available for your participation in this research study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

You have the right to leave this study at any time and for any reason. The study staff will continue to treat you the same no matter what you decide. You will not give up your legal rights by signing this informed consent form (ICF). You also have the right to know about any new information from this study or other studies. This information may affect your health, welfare, or decision to stay in this study.

If you have questions about your rights as a study participant, you may contact any of the ethical committees below:

Mbeya Ethical Review Committee (MMREC)
Mbeya Medical Research and Ethics Committee
Hospital Hill Road, P.O. Box 419
Mbeya, Tanzania

Tel: +255 250 3456/2503351

Fax: 255 250 3577

Website: info@mzrh.go.tz

National Health Research Ethics Committee (NatHREC)/ Medical Research Coordinating Committee (MRCC)
National Institute for Medical Research (NIMR)
P.O.Box 9653
Dar es Salaam, Tanzania

Tel: +255 22 2121400

Fax: 255 22 2121360

Website: www. nimr.org.tz

Walter Reed Army Institute of Research Human Subjects Protection Branch (WRAIR HSPB)
503 Robert Grant Dr., Silver Spring, MD 20910
Tel: (301) 319-9940
E-mail: usarmy.detrick.medcom-wrair.mbx.hspb@health.mil

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Researchers will make every effort to keep your personal information confidential. A code, which will be known only to study personnel, will be used instead of your name on study records in this study. The code will be stored in a locked place. Only the researchers, medical staff, the Sponsor, and the IRBs involved in the study can access your private information.

Researchers will keep all study information confidential to the extent that is permitted by applicable law. Researchers will not give information to anyone without your written permission, except as mentioned above. For study purposes, you must be willing to have results published or shared with other interested parties (such as local and federal scientists) as long as you are not personally identified.

After the study ends, researchers will keep all the data collected in a secured place. The principal investigator of the study will be responsible for keeping this information secure. If you leave the study, researchers will not collect any new data. Researchers will store the data that was already collected along with the other data from individuals that have completed the study. Data collected from this study will be stored indefinitely, unless IRB approved to be destroyed.

Study Approval and Oversight

Several committees monitor this study. These committees make sure that the study is performed ethically and with scientific merit. These committees also make sure that participants are not being hurt by participating in the study and that participants receive medical care if serious problems develop during the study. The study complies with all U.S. regulations and international guidelines on the conduct of medical research.

The WRAIR IRB, NIMR, MMREC, and the TMDA have reviewed this study. These IRBs and regulatory bodies will follow the study as it progresses to ensure continued compliance with ethical standards. This means that representatives from these IRBs/ethics committees may review research records as part of their responsibility to protect human participants. The sponsor, IRBs, US FDA, and the United States Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) representatives may review the study records and access the confidential information about you.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private by following strict confidentiality measures mentioned throughout this consent form. However, we cannot guarantee total privacy. Organizations that may look at your study records for research, quality assurance, and data analysis include:

- NIMR-Mbeya Medical Research Centre (MMRC), Mbeya, Tanzania, a site where this research is taking place.
- David D. Ho, M.D., Columbia University Vagelos College of Physicians and Surgeons, New York, NY, USA, the sponsor providing study drug 10E8.4/iMab
- National Institutes of Health (NIH), Bethesda, MD, USA which is providing the study drug VRC07-523LS being used in this research.
- U.S. Military HIV Research Program (MHRP), Henry M. Jackson Foundation (HJF) which is conducting the study and providing funding
- Reviewing Institutional Review Boards (IRBs): Walter Reed Army Institute of Research (WRAIR), NIMR, MMREC, TFDA
- Government agencies in the United States of America, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- The US Army Medical Research and Development Command (USAMRDC), Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), which has an obligation to review research funded by the United States Department of Defense (DoD) to ensure participants are being fairly treated in studies funded by the DoD.

The researchers conducting this study and the above listed organizations follow all applicable privacy and confidentiality laws and policies to keep your identifying information private to the extent possible.

WHAT HAPPENS IF I AM INJURED WHILE PARTICIPATING IN THIS STUDY?

If you get sick or injured from taking part in the study, please contact the PI and study team immediately. The cost of the medical treatment and care will be covered by a limited study fund and a study medical insurance policy obtained by MHRP/HJF. You will receive appropriate medical treatment here at the study clinic or you will be referred to a qualified medical facility for further treatment and care. While we anticipate that the insurance policy is more than enough to pay for the costs of care associated with research-related injuries, there is a limit to the amount of coverage available. If the limit is exceeded, costs may be transferred to you. Other than medical care that may be provided and other payments specifically stated in this consent form, there is no other compensation available from this research study. However, you should also be made aware that this is not a waiver or release of your legal rights. You have the right to pursue legal remedy if you believe that your injury justifies such action.

You should discuss this thoroughly with the Principal Investigator or site clinicians before making a decision to participate in this study.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again or refer back to it.

CONSENT TO FUTURE RESEARCH

You have been provided information about the option to consent to have your samples and data stored for future unknown research in section 'Future use of your samples and data in other research studies' above. These are not required for you to participate in this study and are completely optional. You may change your mind about these choices at any time during the study.

Please select the options of your choice below by adding your initials to your choices:

1. I consent to have my samples and data stored for future unknown research.

_____ Yes, I agree. _____ No, I do not agree.

Initials Initials

2. I consent to have my samples and data (that is stored for future unknown research) used in genetic research testing.

_____ Yes, I agree. _____ No, I do not agree.

Initials Initials

RV 584 INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN THE STUDY

Signature of Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Printed Name of Participant	Signature of Research Participant	Date

Signature of Individual Administering Consent:

Printed Name of Administering Individual	Signature of Administering Individual	Date