Protocol Title: A Phase 1, Open-Label, Dose-Escalation Study to Evaluate Safety and Pharmacokinetics of a Human Bispecific Antibody VRC-HIVMAB0121-00-AB (CAP256J3LS) Administered Intravenously or Subcutaneously to Healthy Adults

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PRINCIPAL INVESTIGATOR: LaSonji Holman, FNP

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STUDY SITE: NIH Clinical Center

Cohort: Healthy Volunteer

Consent Version: 12/10/2025, Version 5.0

WHO DO YOU CONTACT ABOUT THIS STUDY?

PRINCIPAL INVESTIGATOR: LaSonji Holman, FNP., 301-326-6718; holmanl@mail.nih.gov

STUDY COORDINATOR: Laura Novik, R.N., 301-920-4043; lnovik@mail.nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

This is a study of an experimental product called CAP256J3LS (study product), which means that it has not been approved by the U.S. Food and Drug Administration (FDA) to prevent or treat human immunodeficiency virus (HIV) infection.

The study product targets HIV in two sites at the same time. Antibodies are proteins naturally made by our bodies to protect us from various threats like viruses or bacteria.

A monoclonal antibody means that all the antibodies are exactly the same and have been made in the lab. The study product is a bispecific antibody. "Bispecific" means that it is designed to bind in two different areas on the HIV virus at the same time and prevent the virus from infecting cells.

The main purpose of this study is to see if the study product is safe and how your body responds to it. Since this is the first time the study product will be given to people, we do not know how your body will respond. We also want to check if your body will recognize the study product and make an immune response to it. You cannot get HIV from the study product.

About 50 to 60 people will take part in this study at the NIH Clinical Center in Bethesda, MD. If you decide to take part, you will be enrolled into 1 of 6 groups. Each group will get the study product in 1 of 2 ways, and either 1 or 3 times. You will get the study product either in a vein in your arm, or as a shot under your skin.

If you are in a group that gets the study product one time, you will stay in the study for about 6 months. If you are in a group that gets it three times, you will stay in the study for about 11 months.

If you have side effects from the study product, we expect them to be like the side effects that occur with similar HIV monoclonal antibodies that we have tested or like the monoclonal antibodies that are given to treat other conditions. These side effects usually happened in the first few hours or days after these antibodies were given and included local symptoms (at the injection site) such as pain, redness, swelling, and itching. Redness at the injection site may last up to 6 weeks. You may also have tiredness, body aches, headache, chills, nausea, and joint pain. Other side effects that may occur rarely include trouble breathing, general itchiness, rash, hives, swelling, change in heart rate, or chest pain.

Some bispecific antibodies have a risk of serious allergic reactions that can be life threatening.

During this study, we will collect blood samples from you. Some of your blood will be stored for future research. You will be compensated for your time and inconvenience for taking part in this study. You will not benefit from this study.

If you are a woman who can get pregnant and want to be in this study, you must be willing to use an effective birth control method and not become pregnant, beginning at least 21 days before enrollment, and continuing through the end of the study.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE 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. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

HIV infection is a serious disease with no cure or vaccine to prevent it. Researchers have been working hard to figure out new ways to treat or prevent HIV infection. Using antibodies is one way to prevent HIV infection that seems promising. Antibodies are naturally made by the body to fight germs so that people remain healthy. This study will test an antibody called CAP256J3LS (study product). The study product has been tested in the lab and was found to block HIV-like viruses. The U.S. Food and Drug Administration (FDA) only allows it to be used for research because it is an experimental product.

This study is the first time the study product is tested in humans. The goals of this study are:

- To see if the study product is safe and well-tolerated.

- To measure the amount of the study product that can be found in your blood after you get it and see how the levels of the study product change over time.
- To check if your body will recognize the study product and make an immune response to it.

WHAT WILL HAPPEN DURING THE STUDY?

The study will have 6 groups as shown below. The first 4 groups will each have 10 people in them, and the last two groups will have 5 people each. More people may be enrolled if we need to learn more about safety or how long the study product stays in your blood.

Different groups will get different amounts of study product. Some groups will get one dose, and some will get 3 doses. The study product will be given to you in a vein in your arm, intravenously (IV) or under your skin into the belly fat, by subcutaneous (SC) injection (shot). You will need to stay in the clinic for up to 8 hours on the day(s) the study product is given. Other clinic visits will take about 1 to 2 hours. This will allow us to see if the amount of study product is safe and how long it lasts in your body. If you are unwell or have ongoing symptoms, you will be asked to remain in the clinic until evaluation and discharge by a study clinician. Based on your symptoms, this may include staying overnight in the hospital.

Study Product Administration Plan					
Group	**Number of Participants**	**CAP256J3LS Dose and Route**	**Dosing Schedule**		
			Day 0	**Week 12**	**Week 24**
1	10	5 mg/kg IV	X		
2	10	5 mg/kg SC	X		
3	10	20 mg/kg IV	X		
4	10	40 mg/kg IV	X		
5	5	5 mg/kg SC	X	X	X
6	5	20 mg/kg IV	X	X	X
Total	50*	*Enrollment up to a total of 60 subjects is permitted			

The study will include 14 visits over about 6 months for people in Groups 1-4, because they will only get the study product once.

The study will include about 27 visits over about 11 months for people in Groups 5 and 6, because they will get the study product three times.

We also want to see the differences between getting the study product by IV infusion or SC shot.

We will weigh you on the day you get the study product. Your body weight will be used to calculate the amount of study product we give you each time you get it.

The study will open with the lowest dose of study product. The dose groups are spaced out to allow the study team to look over the safety data in each group. If there are no safety concerns in the lowest dose, then the next higher dose groups will be enrolled. This pattern will continue until all dose groups are enrolled.

Before the study product is given, anyone who can become pregnant will take a pregnancy test. The result of the pregnancy test must be negative before the study product is given.

IV Dosing (Groups 1, 3, 4, 6)

If you are assigned to Groups 1, 3, 4, or 6, a thin tube will be placed in your arm vein (an IV line) on the day you are to get the study product. We will place a second IV line in your other arm for blood sample collection. The study product will be given directly into your vein using a pump with the IV line to control how fast it goes in. The goal is to give the study product in about 1 hour, but it may take longer. If you have side effects, we may stop or slow down the infusion rate. We will collect blood samples as soon as the infusion ends and then 1, 2, and 4 hours after the infusion. You may be allowed to leave the clinic after 2 hours if there are no safety concerns, but you must return for a blood draw 4 hours after you received the study product.

If you are in Groups 1, 3, or 4, we will collect about 11 tubes (or 4 tablespoons) of blood and a urine sample on the day you get the study product, before the infusion starts. We will collect 4 more tubes of blood, one tube as soon as the infusion ends, and then one at 1, 2, and 4 hours after that. Each of these 4 tubes will have about 1 teaspoon of blood.

If you are in Group 6, you will get the study product three times during the study. The first time that you get the study product, we will collect about 11 tubes (or 4 tablespoons) of blood and a urine sample on the day you get the study product, before the infusion starts. We will collect 4 more tubes of blood, one tube as soon as the infusion ends, and then one at 1, 2, and 4 hours after that. Each of these 4 tubes will have about 1 teaspoon of blood.

The second and third times you get the study product in Group 6, we will collect about 4 tubes (or about 2 tablespoons) of blood and a urine sample on the day you get the study product, before the infusion starts. We will collect 2 more tubes of blood, one tube as soon as the infusion ends, and then one at 1 hour after that. Each of these 2 tubes will have about 1 teaspoon of blood.

SC Dosing (Groups 2 and 5)

If you are assigned to Groups 2 or 5, we will use a small needle to inject the study product into the fatty area of your belly, under your skin. We may use your arm or thigh area instead. You will get 1 – 4 injections to make one full dose, depending on your weight. We will monitor you for at least 1 hour after you get the study product. If there are no safety concerns, you will be allowed to leave the clinic after the safety check.

If you are in Group 2, we will collect about 11 tubes (or 4 tablespoons) of blood and a urine sample on the day that you get the study product.

If you are in Group 5, you will get the study product two more times during the study. We will monitor you in the clinic for at least 1 hour after you get the 2nd and 3rd doses of the study product. The first time you get the study product, we will collect about 11 tubes (or 4 tablespoons) of blood and a urine sample; the other two times you get the study product, we will collect about 4 tubes (or about 2 tablespoons) of blood and a urine sample.

For all groups: We will give you a measuring tool and thermometer to take home with you. You will need to check your temperature every day for 7 days after you get the study product and record your highest temperature and any symptoms you have. You will use the measuring tool to measure any redness, swelling, or bruising you may have at the injection site. We will give you a password to a secure website to record this information. If you do not have a computer, you may use a paper diary instead.

You should tell a study nurse or doctor, as soon as possible, if you have any side effects after you get the study product. You can reach us by phone 24 hours a day, seven days a week. If you have symptoms, you may need to come into the clinic for a physical exam before your next scheduled visit. It is very important that you follow the instructions from the clinic staff.

Follow-up visits: We will check you for any health changes or problems at each visit. We will ask you how you are feeling and if you have taken any medications. We will draw about 2 to 6 tubes (or 1 to 2 tablespoons) of blood at each study visit. At some of those visits we will also collect a urine sample. We will tell you right away if any of your test results show a health problem.

We will use some of the blood samples to study if your body develops an immune response to the study product. These tests are for research purposes only and are not for checking your health. We will not give you these results. After completing this study, we may invite you to take part in another study for follow-up sample collection.

Clinical studies follow a set schedule. This helps us answer the research questions. The visit schedule is a little flexible, but it is important that you work with the staff to follow the schedule as closely as possible. You should try to not miss any visits.

HIV TESTING AND COUNSELING

HIV risk-reduction counseling and testing will be provided to you if you take part in this study. We will test you for HIV. We will tell you how to avoid getting HIV and give you prevention tools. If you are infected with HIV, you will not be able to get the study product. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners who may be at risk because of your HIV infection.

If you have questions about HIV testing, you should discuss them with the study nurse or doctor. You may also call an NIH Clinical Center HIV counselor at 301-496-2381.

MONITORING OF THE STUDY

A group of physicians and scientists at NIH will closely monitor safety in this study. This group will review the information from the study and will pay close attention to possible harmful reactions. If serious side effects occur, we may delay or stop giving the study product(s).

GENETIC TESTING

Some of the blood drawn from you as part of this study will be used for genetic tests. Some genetic tests are done in research studies to see if genetic differences in people cause different types of immune responses. The blood sample used in these genetic tests will not have your name on it and the results will not be in your medical record. These tests are not used to check your health, and we will not tell you the results.

The genetic testing done in this study is for research purposes only. Any genetic information collected or learned about you will be kept confidential.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study and get the study product 1 time in Groups 1-4, you will stay in the study for about 6 months. If you get the study product 3 times in Groups 5 or 6, you will stay in the study for about 11 months.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

50 to 60 people will take part in this study at the NIH Clinical Center in Bethesda, Maryland.

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

Risks of CAP256J3LS: This study is the first time the study product will be given to people.

The safety data described below is taken from studies with monoclonal antibodies that are like CAP256J3LS. Most side effects tend to happen within the first 1-3 days after you get the antibodies. Side effects to those monoclonal antibodies given by IV included fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, tiredness, trouble breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heart, or chest pain. You may also have these symptoms after receiving CAP256J3LS. These symptoms usually go away within a few minutes to hours after you get the study product. We are giving the study product at a controlled rate. If you develop symptoms while the study product is being given, then tell the nurse right away. Slowing down the infusion rate or stopping it, may help improve your symptoms.

Side effects to similar monoclonal antibodies given by injection under the skin (subcutaneously) included pain/tenderness, itchiness, redness and/or swelling at the site of injection. Tiredness, muscle pain outside the injection site, and headache have also been reported. You may also have these symptoms after receiving CAP256J3LS.

A low white blood cell count (lymphocytopenia) was commonly seen in people who got a different study product called CAP256V2LS, a monoclonal antibody that is like CAP256J3LS (the study product in this study). White blood cells help the body fight infection and disease.

In previous studies involving the other similar monoclonal antibody mentioned above (CAP256V2LS), low white blood cell counts were seen for a short time after people got the product by IV infusion or shot. This temporary drop in white blood cells did not have any lasting effects. Some people had temporary increased levels for two tests related to liver function, ALT and AST. Some people also had temporary increases in the amount of protein in their urine. This also had no lasting effects.

Some antibodies that target human cells change how the immune system works and can increase a person's risk for infections. The study product targets a virus and is not expected to increase the risk of infections. Some antibody products have a risk of serious allergic reactions that can be life-threatening. Anaphylaxis is one type of allergic reaction that may happen soon after a bispecific antibody product is given. This reaction can include difficulty breathing, low blood pressure, hives, rash, or swelling in the mouth and face.

Some people in this trial will receive multiple doses of the study product. Rarely, some reactions may happen several days or weeks after the study product is given, including hives, rash, fever, enlarged lymph nodes, muscle pain, or joint pain. Painful local swelling and redness may also occur several hours to several weeks after the study product is given for a second or third time by subcutaneous injection.

Participation in this study may affect your eligibility for future bispecific antibody studies. We will give you any new information about risks or other information that may affect your decision to continue in this study, as it becomes available.

You may not donate blood while taking part in this study and you may not donate blood for one year after the date of your last dose of the study product.

Unknown risks: the study product may have other side effects that are not yet known.

Risks of IV or SC dosing: General risks of methods that use a needle include localized stinging, discomfort, pain, soreness, redness, itching, bruising, and swelling. If you are in a group that gets the study product by IV infusion, the IV lines may remain in your veins for about 6 hours. Problems at the IV site are usually mild and may include pain, bruising, minor swelling, or bleeding. Rarely, there may be an infection, vein irritation, nerve problem, or blood clot.

Risks of blood drawing: Blood drawing may cause pain, bruising, feeling lightheaded, or fainting. Rarely, it may cause infection at the site where the blood is taken, vein irritation, nerve problems, or blood clot.

What are the risks related to pregnancy?

We do not know how the experimental bispecific antibody may affect a fetus or nursing infant. For this reason, women who can become pregnant must have a negative pregnancy test before getting the study product. They must also agree to use effective birth control starting at least 21 days before starting the study and continue using it until the end of the study. We will discuss effective methods of birth control with you.

You must tell the clinic staff right away if you become pregnant, if your birth control method fails, or if you think that you might be pregnant during the study. If you are pregnant, you will be asked to continue with follow-up visits so that we can check your health, but you will not receive any more doses of the study product if you are in Groups 5 or 6. We will ask you the outcome of the pregnancy.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Are there any potential benefits to others that might result from the study?

Others may benefit in the future from the information that will be learned from the study.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Instead of being in this study, you could choose not to take part. You may be eligible for other Vaccine Research Center studies.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

At each visit, you will be checked for any health changes or problems. Blood will be drawn at many study visits to check on your health. You will be told right away, either by phone call or text if any of your test results show a health problem.

The results of this study may be reported in medical journals, on the internet or at scientific meetings. We will give you information about how to find the study results once they are available.

EARLY WITHDRAWAL FROM THE STUDY

You may be removed from the research study by the researchers for any of the following reasons:

- You don't keep appointments or follow study procedures.
- You get a serious illness that needs ongoing medical care.
- You need to get treatment with a medication that affects your immune system (such as a steroid like prednisone).
- The researcher believes that it is in your best interest to remove you from the study.
- The study is stopped by regulatory agencies, the study sponsor, or study researchers. If this happens, we will tell you why.

If you agree to take part in this study, it is important that you keep all your appointments. Your participation in this study is completely voluntary. You can choose to stop taking part in the study at any time. There is no penalty or loss of benefits if you choose to leave the study.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved by the study team for use in other studies?

As part of this study, we are obtaining specimens and data from you. We plan to store and use these specimens and data for studies other than the one described in this consent form that are going on right now, as well as studies that may be conducted in the future. The specimens and data will be kept in a way that we will still know that they came from you (i.e., they will be identifiable to us). If we use your identifiable specimens or data for future research, our study

will be reviewed and approved by an Institutional Review Board who will make sure that we are protecting your confidentiality. These future studies might help us better understand other diseases or conditions. This could include studies to develop other research tests, treatments, products, or devices that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you agree to take part in this study, you give permission for your coded specimens and data to be stored and used for future research as described above.

Will your specimens or data be shared with other researchers for use in other studies?

We may share your specimens and data with other researchers. The other researchers may be doing studies in similar areas to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or at commercial entities.

One way that we may share your data is by putting it into a large database called a repository, which is a way to make it widely available to the research community. If we do place your data in a repository, it will be labeled with a code, (not with your name or other information that could be used to easily identify you). Even though it will only be labeled with a code, some types of data, in particular data about your genes (called genetic or genomic data), can be used to figure out who you are, although this is difficult to do, and we think it is unlikely to happen.

The data in the repository will only be available to qualified researchers. These researchers must receive permission before they are allowed to access the data. Before receiving the data, the researchers must promise that they will not try to figure out the identity of the research participants.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data is to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

In addition to the planned use and sharing described above, we might remove any labels from your specimens and data that might identify you (i.e., anonymize them), and use them or share them with other researchers for future studies at the NIH or other places. When we or the other researchers use your anonymized specimens and data for these projects, there will be no way to know that they came from you. We want to make sure that you understand that this is a possibility if you take part in this study. Once we do this, we would not be able to remove your specimens or data from these studies or prevent their use in future studies because we would not be able to tell which specimens or data belong to you.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others who should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information

that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known, or that no one will gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

Can you change your mind about use and sharing for future research?

If you change your mind and do not want us to store and use your specimens and data for future studies, you should contact the study team. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data is already complete, the information from that research may still be used. Also, if the specimens and data have been shared already, it might not be possible to withdraw them.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

PAYMENT

Will you receive any type of payment for taking part in this study?

You will be compensated for your time and inconvenience. Total compensation for completion of the study will be between $2,740 to $5,885 and is based on the number and type of study visits you complete. You will get:

- $200 for follow-up visits with a blood draw.
- $85 for clinic visits without a blood draw.
- $430 for visit(s) where you get the study product by IV infusion
- $375 for visit(s) where you get the study product by injection (shot)
- $25 total for timely completion of all 7 days of an electronic diary.

You will get the compensation about 2 weeks after each completed visit by direct deposit into a bank account that you specify to the Volunteer Payment Office.

The study team will need your social security number to compensate you. If you don't provide your social security number, you can still take part in the research study, however you may not be able to receive compensation.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

If you are unable to finish the study, you will receive compensation for the parts you completed. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically withheld to repay that debt on your behalf.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

This study does not offer reimbursement to participants, or payment of, hotel, travel, or meals.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study have developed a bispecific antibody, CAP256J3LS, which is being used in this study. This means it is possible that the results of this study could lead to payments to NIH. You will not receive any money from the development of CAP256J3LS.

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We do our best to keep your medical information private. However, we cannot promise this. Certain groups may look at and copy your medical records. This may be for research, quality and data review including:

- The NIH and other government groups. (For example, the Food and Drug Administration (FDA) to help keep research safe.)
- NIH Institutional Review Board
- The study Sponsor Vaccine Research Center or their agent(s)

NIH and researchers doing this study follow special laws and policies to keep your information as private as possible. However, your identity and information about being in this study may accidentally be seen by others.

In most cases, NIH will not share any identifiable information about you unless you say it is okay in writing. More information about sharing your information is below.

Information gathered for this study is protected under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, NIH has a Certificate of Confidentiality (Certificate). With this Certificate, researchers may not release or use information about you except in certain cases.

NIH researchers must not share information that may identify you in any legal proceedings, such as if a court requests it with a subpoena.

The Certificate does not protect your information when it:

1. is shared with people connected with the research. For example, information may be used for internal reviews by NIH; or
2. is required by law to be disclosed. For example, information may be shared with the FDA or with public health agencies.
3. is for other research if allowed by other regulations;
4. is shared with your consent.

Researchers may provide your information when you say it is okay. The Certificate does not keep you from sharing your own information.

The Certificate will not prevent telling authorities about harm to yourself or others. Examples are child abuse and neglect.

Privacy Act

The Privacy Act helps keep your NIH medical information confidential. In some cases, it is different from the Certificate. Sometimes the Privacy Act allows sharing your information without your permission. An example is if Congress requests it.

Information may also be shared for some research. It can be given to some federal and state agencies. It can be used for HIV partner notification, or for infectious disease, abuse, or neglect reports. It may be shared with tumor registries, for quality and medical reviews. It may also be shared if NIH is involved in a lawsuit. However, NIH will only release medical record information if allowed by both the Certificate and the Privacy Act.

RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, LaSonji Holman, FNP, holmanl@mail.nih.gov, at 301-326-6718. Another researcher you may call is Laura Novik, R.N., lnovik@mail.nih.gov, at 301-920-4043.

You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713 if you have a research-related complaint or concern.

CONSENT DOCUMENT

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

Adult Research 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.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.