Protocol Title: VRC 615: A Phase I, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of a Human Monoclonal Antibody, VRC-HIVMAB0115-00-AB (VRC01.23LS), Administered Intravenously or Subcutaneously to Healthy Adults.

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PRINCIPAL INVESTIGATOR: Lesia K. Dropulic, M.D

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STUDY SITE: NIH Clinical Center

Cohort: Healthy Volunteer

Consent Version: October 16, 2023, Version 2.0

WHO DO YOU CONTACT ABOUT THIS STUDY?

PRINCIPAL INVESTIGATOR: Lesia K. Dropulic, M.D., [redacted]

STUDY COORDINATOR: Laura Novik, R.N., [redacted]

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.

The purpose of this study is to find out if it is safe to give humans an investigational drug called VRC01.23LS. We also want to see how the body responds when this drug is given. VRC01.23LS is considered investigational which means that it has not been approved for use by the U.S. Food and Drug Administration (FDA). We are hoping that in the future, we can use this drug to prevent or treat human immunodeficiency virus (HIV) infection. Since this is the first time VRC01.23LS will be given to people, we do not know how your body will respond. You cannot get HIV from VRC01.23LS.

VRC01.23LS is a broadly neutralizing monoclonal antibody (mAb) that targets HIV. Antibodies are proteins naturally produced by our bodies to protect us from various organisms, viruses or bacteria, for example. A monoclonal antibody means that it was produced in the laboratory. "Broadly neutralizing" means that it is designed to bind to different HIV strains and prevent them from infecting cells.

About 22 to 40 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. You will get 1 or 3 doses of VRC01.23LS either in a vein in your arm, or as an injection under the skin. The way you are

given the drug and the number of times you get it will be based on which group you are assigned to. If you are in a group that gets VRC01.23LS 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.

Since this is the first time we are giving humans VRC01.23LS, we are not sure what side effects might happen, but we expect them to be like the side effects that occur with similar HIV mAbs tested in other clinical trials or similar to mAbs that are used to treat other conditions. These side effects usually happen in the first few hours or days after the mAb is given and include 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, or chest pain.

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

If you are able to 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.

During the study and screening for the study, we will collect blood samples and data from you. Some of your blood samples and data will be used in this study and will be stored for future research.

You will not benefit from this study.

You will be compensated for your time and inconvenience for taking part in this 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 be under consideration 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. We are asking you to join this research study because you are a healthy adult and are interested in participation.

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 VRC01.23LS. VRC01.23LS has been tested in the lab and was found to block HIV-like viruses.

VRC01.23LS is considered investigational, which means that it has not been approved for use by the U.S. Food and Drug Administration (FDA).

This study is the first time VRC01.23LS will be tested in humans. The goals of this study are:

- To see if VRC01.23LS is safe and well-tolerated.
- To measure the amount of VRC01.23LS that can be found in your blood after you get it and how the levels of VRC01.23LS change over time.
- To check if your body will recognize VRC01.23LS and make an immune response to it.

WHAT WILL HAPPEN DURING THE STUDY?

The study will have 6 groups as shown in the table below. The first 4 groups will each have about 3 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 about how long the mAb stays in your blood. Different groups will get different amounts of VRC01.23LS. Some groups will get one dose, and some will get 3 doses. VRC01.23LS will be given into a vein in your arm, intravenously (IV) or into the belly fat under your skin, subcutaneously (SC) This will help us learn if there are differences in how the body reacts to the drug based on how it is given.

You may need to stay in the clinic for up to 8 hours on the day(s) VRC01.23LS is given. This will allow us to see if the dose of the antibody is safe and how long it lasts in the body. If you are feeling unwell or have ongoing side effects, you will be asked to remain in the clinic until evaluation and discharge by a study clinician. This may include the possibility of an overnight inpatient stay if medically indicated for ongoing side effects. Other clinic visits will take about 1 to 2 hours.

VRC 615 Study Groups					
Group	Number of Participants	Dose and Route	Dosing Schedule		
			Day 0	Week 12	Week 24
1	3	5 mg/kg IV	X		
2	3	5 mg/kg SC	X		
3	3	20 mg/kg IV	X		
4	3	40 mg/kg IV	X		

VRC 615 Study Groups					
Group	Number of Participants	Dose and Route	Dosing Schedule		
			Day 0	Week 12	Week 24
5	5	5 mg/kg SC	X	X	X
6	5	20 mg/kg IV	X	X	X

The study will include 13-14 visits over about 24 weeks for people in Groups 1-4, because they will only get VRC01.23LS once.

The study will include about 25 visits over about 48 weeks for people in Groups 5 and 6, because they will get VRC01.23LS three times.

You will be weighed on the day VRC01.23LS is to be given. Your body weight will be used to calculate the amount of VRC01.23LS each time you get it.

The study will open with the lowest dose of VRC01.23LS. 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. You cannot choose which group you are assigned to.

Before VRC01.23LS is given, all subjects who are able to become pregnant will take a pregnancy test. The result of the pregnancy test must be negative before VRC01.23LS is given.

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

If you are assigned to Groups 1, 3, 4, or 6, we will use a needle to place a thin tube (IV) in your arm vein on the day you are to get VRC01.23LS. We will place a second IV line in your other arm for blood sample collection. VRC01.23LS will be given directly into your vein using a pump to control how fast it goes in. The goal is to give VRC01.23LS in about 30 minutes, but it may take longer if you have side effects because the pump may be slowed down or stopped. 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 VRC01.23LS.

If you are in Groups 1, 3 or 4, we will collect about 11 tubes of blood (55 mL or about 4 tablespoons) on the day that you get the study product.

If you are in Group 6, you will get VRC01.23LS two more times during the study. The first time you get the study product, we will collect about 11 tubes of blood (55 mL or about 4 tablespoons); the other two times you get VRC01.23LS, we will collect about 6 tubes of blood (19 mL or about 1 tablespoon) from you.

SC Dosing (Groups 2 and 5)

If you are assigned to Groups 2 or 5, we will use a small needle to inject VRC01.23LS into the fatty area of your belly, under your skin. We may use your arm or thigh area instead. You will get 1 to 4 of these injections for each dose. We will monitor you for at least 1 hour after you get VRC01.23LS. 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 7 tubes of blood (55 mL or about 4 tablespoons) on the day that you get the study product.

If you are in Group 5, you will get VRC01.23LS 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 VRC01.23LS. The first time you get the study product, we will collect about 7 tubes of blood (55 mL or about 4 tablespoons); the other two times you get VRC01.23LS, we will collect about 4 tubes of blood (19 mL or about 1 tablespoon) from you.

For all groups: We will give you a measuring tool and thermometer and ask you to check your temperature every day for 7 days after you get the study product. You will need to 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. You will get a password to a secure website to record this information. If you do not have a computer, you may use a paper diary instead to record this information.

You should tell a Vaccine Research Center (VRC) nurse or doctor, as soon as possible, if you have any side effects after you get the study product. You can reach the staff 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: These visits will last 1 to 2 hours. We will check you for any health changes or problems at each visit. We will also ask you how you are feeling and if you have taken any medications. We will draw about 1 to 5 tubes of blood at each study visit. Some of these tests will be used to make sure you are not having any side effects from the drug. We will tell you right away if any of your test results show a health problem.

We will also use some of the blood samples to see if your body develops an immune response to VRC01.23LS. These tests are for research purposes only and are not for checking on 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 remain HIV-uninfected and give you prevention resources. If you are infected with HIV, you will not be able to receive VRC01.23LS. 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, further dosing with the study product may be delayed or canceled.

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 performed 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, your participation will last about 24 weeks. If you get the study product 3 times, your participation will last about 48 weeks.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

Twenty-two (22) to 40 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 VRC01.23LS: This study is the first time VRC01.23LS will be given to people.

The safety data described below is taken from studies with other mAbs that are like VRC01.23LS. Most side effects tend to happen within the first 1-3 days after product administration. Side effects to VRC01.23LS -like antibodies given by IV infusion may include fever, chills, shaking, nausea, vomiting, pain, headache, dizziness, trouble breathing, high or low blood pressure, itchiness, rash, hives, lip or face swelling, diarrhea, racing heart, or chest pain. These symptoms usually go away

within a few minutes to hours after the product is given. We are giving VRC01.23LS at a controlled rate. If you develop symptoms while VRC01.23LS is being given, then tell the nurse right away. Slowing down how fast VRC01.23LS is going into your body or stopping the flow may help improve your symptoms.

Side effects to VRC01.23LS-like antibodies given SC, under the skin may include pain/tenderness, itchiness, redness and/or swelling at the site of injection.

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 an mAb product is given. This reaction can include difficulty breathing, low blood pressure, hives, rash, or swelling in the mouth and face.

Serum sickness is a type of reaction that may happen several days or weeks after an antibody is given. This reaction may include hives, rash, fever, enlarged lymph nodes, muscle pains, or joint pains.

Some antibodies of the type that change how the immune system works can increase a person's risk for infections. VRC01.23LS is not expected to increase the risk of infections, because it attacks a virus and does not target the human immune system.

Unknown risks: VRC01.23LS may have other side effects that are not yet known. Participation in this study may affect your eligibility for future mAb 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 VRC01.23LS.

Risks of IV or SC dosing: General risks of methods that use a needle include stinging, discomfort, pain, soreness, redness, bruising, swelling or a tiny cut at the needle insertion site.

Risks of blood drawing: Blood drawing may cause pain, bruising, and may cause a feeling of lightheadedness or fainting. Rarely, it may cause infection at the site where the blood is taken. If you are in a group that gets VRC01.23LS 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.

What are the risks related to pregnancy?

We do not know how the experimental mAb may affect a fetus or nursing infant. Therefore, if you are able to become pregnant, you must have a negative pregnancy test before product administration and agree to use effective birth control beginning at least 21 days before the first injection 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 become pregnant during your participation in this study, 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 VRC01.23LS if you are in Groups 5 or 6. You will not have any research blood drawn during your visits. We will ask you the outcome of your pregnancy after your delivery.

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 VRC 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 research tests are not intended for checking your health and will not be returned to you.

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 researcher 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 become pregnant;
- You need to get treatment with a medication that affects your immune system (such as a steroid like prednisone);

- If 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 investigators. If this happens, we will tell you why.

If you agree to take part in this study, it is important for you to keep all of 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 for use in other / future research 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 and 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, drugs, 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.

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.

If we do share your specimens or data, we will know that the specimens and data came from you. However, the other researchers will not know that they came from you (i.e., they will be de-identified).

If you agree to participate in this study, you give permission for your coded / de-identified specimens and data to be stored and used in other and future research studies as described above.

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 participate 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.

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

If you change your mind and do not want us to use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee it. For example, if research with your specimens and/or 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 by the NIH?

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

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 by removing 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 someone may 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.

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 $2630 to $5705 and is based on the number and type of study visits you complete. You will get:

- $200 for scheduled visits with a blood draw.
- $85 for clinic visits that do not include a blood draw.
- $430 for IV product administration visit(s)
- $375 for SC product administration visit(s)
- $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 numbers, you can still take part in the research study, however you may not be able to receive compensation

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 reduced 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 for 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 Conflict of Interest (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 developed the mAb, VRC01.23LS, that is used in this study. This means it is possible that the results of this study could lead to payments to NIH. By law, the government is required to share such payments with the employee inventors. You will not receive any money from the development of VRC01.23LS.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

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. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.

- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor Vaccine Research Center, or their agent(s)

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy

Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING 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, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Lesia K. Dropulic, M.D., [redacted] Another researcher you may call is Laura Novik, R.N., at [redacted] You may also call the NIH Clinical Center Patient Representative at [redacted] or the NIH Office of IRB Operations at [redacted] 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: _____.