PRINCIPAL INVESTIGATOR: Mark Roschewski, M.D.

STUDY TITLE: A Phase 1 Study of Venetoclax added to Magrolimab and Obinutuzumab for Relapsed and Refractory Indolent B-cell Malignancies

STUDY SITE: NIH Clinical Center

Cohort: Screening consent, Affected patient

Consent Version: 05/16/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Mark Roschewski, M.D.
Phone: 240-760-6183
Email: mark.roschewski@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.

You are being asked to take part in this study because you have an indolent B-cell lymphoma and your disease has returned or progressed after other treatment.

This consent is for "screening." This part of the study will allow us to find out if you are able to take part in the treatment part of the study.

The main purpose of this study is to find out if it is safe to give the combination of three drugs – magrolimab, obinutuzumab, venetoclax – to patients with B-cell lymphomas. Specifically, we will look at patients with follicular lymphoma (FL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL).

Although obinutuzumab (GAZYVA®) and venetoclax (VENCLEXTA™) have been approved and used either alone or in combination to treat types of lymphoma, magrolimab has not. **The use of magrolimab in this research study is experimental, which means that the FDA has not approved its use for cancer treatment or treatment of any other disease**. In addition, **the combination of magrolimab, obinutuzumab, venetoclax in this study is experimental**, which means that while the FDA has approved obinutuzumab and venetoclax for cancer treatment, they have not approved the combination of obinutuzumab and venetoclax with magrolimab.

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We want to study the side effects of these drugs when given together. We also want to see if the combination of these drugs is an effective treatment for your disease, and hope to learn about how they work together to treat B-cell lymphomas.

If you decide to be screened for this study, here are some things that will happen:

- We will review your health history, prior tests and biopsy samples that you have had taken before, or take a new biopsy if needed, and will perform tests to find out whether you are able to take part (screening) in the study. Some of tests to be done include a physical examination, blood and urine tests, bone marrow testing, and imaging (such as CT, MRI, and PET/CT scans).
- Some possible side effects from the screening tests for include bruising, bleeding, and pain where samples are taken (such as blood and biopsy), and discomfort with the procedures.
- We do not know which side effects you will experience.

There may be no direct benefit to you from taking part in the study. This screening part will help us decide if you are able to take part in the next step of this research study. You will also have the benefit of seeing our NIH doctors to discuss your treatment. If you would like, we can share the results of these screening tests and notes with your personal physician.

The screening portion of this study will take between a few days and a week. If you move on to the treatment portion of the study, you may be in the study for several years depending on how you tolerate the treatment. You can stop taking part in the trial at any time.

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 treatments they would want to receive (such as blood transfusions). 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?

This part of the study is to determine if you are suited for this study.

B-cell lymphoma is a cancer of certain white blood cells (called lymphocytes) that are found in lymph nodes and the cancer affects the lymphatic system. The lymphatic system helps to fight infections and disease. The purpose of this research study is to see if the combination of magrolimab, obinutuzumab, and venetoclax is safe and effective at treating different types of B-cell lymphoma. We are asking you to join this research study because you have either follicular

lymphoma (FL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL) or chronic lymphocytic leukemia (CLL) and your disease has returned or progressed.

Additional information is provided about each of the drugs being combined for the purposes of this study:

- Venetoclax (VENCLEXTA™) is a drug that targets a specific protein in the body called BCL-2. When normal cells are damaged or old, your body tells them to self-destruct. This natural process is called apoptosis. In some lymphomas, BCL-2 may build up and prevent cancer cells from self-destructing naturally. By targeting BCL-2 with venetoclax, the process of apoptosis may be restored, allowing your body to destroy cancer cells.
- Obinutuzumab (GAZYVA®) is a type of drug called a "monoclonal antibody". It is believed that obinutuzumab works by targeting a specific protein in the body called CD20. CD20 is found on the surface of B-cells in the body, often in high amounts in some types of lymphoma. By using obinutuzumab to target CD20 and attach to it, it may work by causing the cell to die or by signaling your immune system to destroy the cancer cells.
- Magrolimab is also a "monoclonal antibody". It is believed that magrolimab works by targeting a specific protein in the body called CD47. CD47 is a protein on the surface of cancer cell that sends a "do not eat me" signal to the body's immune system. Blocking this protein with an anti-CD47 antibody such as magrolimab may allow the body's immune system to recognize and kill these cancer cells.

Although obinutuzumab (GAZYVA®) and venetoclax (VENCLEXTA™) have been approved and used either alone or in combination to treat types of lymphoma, magrolimab has not. **The use of magrolimab in this research study is experimental, which means that the FDA has not approved its use for cancer treatment or treatment of any other disease**. In addition, **the combination of magrolimab, obinutuzumab, venetoclax in this study is experimental**, which means that while the FDA has approved obinutuzumab and venetoclax for cancer treatment, they have not approved the combination of obinutuzumab and venetoclax with magrolimab. However, the FDA has given us permission to use these drugs together in this study.

We want to study the side effects of these drugs when given together. We also want to see if the combination of these drugs is effective treatment for your disease and hope to learn about how these drug work together to treat B-cell lymphomas.

You may not be eligible for our study for several reasons, such as the presence of certain other diseases, infections, or problems with your organ function. If it is found that you are not suited to take part in the treatment, you will be removed from the study.

WHAT WILL HAPPEN DURING THE STUDY?

All of these tests or procedures are part of your regular care and may be done even if you are not being considered to join the study. If you have had some of these tests or procedures recently, they may or may not have to be repeated. The following tests and procedures are needed to determine whether you are eligible for this trial:

- Medical history: A complete review of your medical history, including obtaining information about your diagnosis and previous treatments, and reviewing information

about your other conditions. If you have medical records from another clinic or hospital, you will be asked to get copies of these records, or your study doctor may be able to request them on your behalf.

- Physical examination: This will include taking your vital signs (such as temperature, blood pressure, heart rate, breathing rate), seeing how you function in your daily activities, any current symptoms of your condition and a review of all medications that you take
- Blood tests: Blood will be drawn from either an arm vein or a central venous access device, if you have one. This will be used for measurements including:
    - Blood counts, liver and kidney function, serum chemistries and other routine tests such as how well your blood clots
    - Tests routinely done in patients with your type of cancer to confirm the status of your disease
    - Hepatitis A, B, and C infection testing
    - HIV: As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will not be able to participate in this study. 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 at possible risk because of your HIV infection
- Pregnancy test: For women who could have children, a pregnancy test will be done (urine or blood sample). You will not be able to participate if you are pregnant.
- Urine tests: Urine will be collected for routine testing (urinalysis), including to check for possible infection.
- Pathology review: A sample of tissue from any previous biopsy will be tested at NCI to confirm your diagnosis, stage, and status of your disease. If no sample is available a fresh biopsy will be required.
- Bone marrow aspiration and/or biopsy: A bone marrow aspiration and/or biopsy will be done prior to starting treatment if not done within the last 12 months since completing the last treatment received to confirm the stage and status of your disease. These are done by numbing your hipbone using a small needle containing local anesthesia, and then a needle will be put into the hipbone, and a small amount of bone marrow will be taken out through the needle
- Imaging: The following scans may be done, as directed by your doctor and based upon your disease: Imaging to show all sites of your disease with imaging scans, such as a CT scan of your chest, abdomen and pelvis, brain MRI and other scans if needed

HOW LONG WILL THE STUDY TAKE?

If you agree to take part, your involvement is expected to last for up to a few weeks on the screening portion. After the evaluations are complete, we will determine if you are eligible to participate in the treatment portion of the study.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 76 people participate in this study at the NIH.

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

The primary risks or discomforts of taking part in screening are those that may be caused by the tests and procedures. The following describes the most common risks of these tests and procedures. Your doctor or nurse will also discuss with you in detail any risks or discomforts of the procedures or test(s) you will be scheduled to undergo.

The risks of taking part may include the following:

- Blood draws:
  - Likely: discomfort, swelling, bruising, and/or bleeding at the site of the needle insertion.
  - Less likely: dizziness or feeling faint.
  - Rare: infection (symptoms may include fever, shaking, chills, fatigue, confusion, joint aches, or rapid pulse).
- Biopsy (if needed):
  - Likely: discomfort or pain, redness, swelling, and/or bruising at the site of the needle insertion.
  - Less likely: Bleeding from the site of the needle insertion
  - Rare: significant infection or bleeding from this procedure, allergic reaction to the anesthetic, or formation of a scar at the site of needle entry.

If you will have sedation with the procedure, these risks will be discussed with you prior to the procedure. You will be asked to sign a separate consent form prior to any biopsy procedure.

- Imaging: The following may be done as directed by your doctor based on your disease:

o CT Scan (computerized tomography): There is a slight risk of developing an allergic reaction to the iodine contrast material. The reaction can be mild (itching, rash) or severe (difficulty breathing or sudden shock). Death resulting from an allergic reaction in this setting is rare. Most reactions can be controlled using drugs. Be sure to tell your doctor if you have allergies of any kind (such as hay fever, iodine allergy, eczema, hives, or food allergies).

The contrast material used during CT scanning can cause water loss or damage to the kidneys that may lead to kidney failure. This is a concern if you have poor kidney function, dehydration, or diabetes, especially if you take Metformin® (Glucophage) to control diabetes.

You may also experience discomfort related to lying still in an enclosed space for a prolonged period of time.

o MRI Risks: MRI uses a strong magnetic field and radio waves to take pictures of the body. We may obtain pictures of your brain or other parts of your body for this study. The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you

will lie on a table that can slide in and out of the cylinder. We will place soft padding or a coil around your head. You will be in the scanner about 45 minutes. You may be asked to lie still for up to 15 minutes at a time. While in the scanner you will hear loud knocking noises, and you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan, and you may ask to be moved out of the machine at anytime.

It is very important for the experiment that you do not move your head or body inside the scanner. We will use padding around your head to help keep it in place.

We may place a bar in your mouth to help keep your head still.

People are at risk for injury from the MRI magnet if they have some kinds of metal in their body. It may be unsafe for you to have an MRI scan if you have pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants, aneurysm clips (metal clips on the wall of a large artery), metal prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, tattoos, an implanted delivery pump, or shrapnel fragments. Welders and metal workers may have small metal fragments in the eye. You will be screened for these conditions before having any MRI scan. If you have a question about metal in your body, you should inform the staff. You will be asked to complete an MRI screening form before each MRI scan you have.

In addition, all magnetic objects (like watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

People with fear of confined spaces may become anxious during an MRI. Those with back problems may have back pain or discomfort from lying in the scanner. The noise from the scanner is loud enough to damage hearing, especially in people who already have hearing loss. Everyone having a research MRI scan will be fitted with hearing protection. If the hearing protection comes loose during the scan, you should let us know right away.

There are no known long-term risks of MRI scans.

<u>Risks for gadolinium enhanced MRI scans:</u>

Procedure: During part of the MRI you may receive gadolinium, a contrast agent, through an intravenous (IV) catheter. It will be done for medical purposes.

It is not known if MRI with contrast is completely safe for a developing fetus. Therefore, all women of childbearing potential will have a pregnancy test performed no more than 24 hours before each MRI scan with contrast. The scan will not be done if the pregnancy test is positive.

Risks: The risks of an IV catheter include bleeding, infection, or inflammation of the skin and vein with pain and swelling.

Mild symptoms from gadolinium infusion occur in fewer than 1% of those who receive it and usually go away quickly. Mild symptoms may include coldness in the arm during the injection, a metallic taste, headache, and nausea. In an extremely small number, fewer than one in 300,000 people, more severe symptoms have been reported including shortness of breath, wheezing, hives, and lowering of blood pressure. You should not receive

gadolinium if you previously had an allergic reaction to it. You will be asked about such allergic reactions before gadolinium is given.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis" which has resulted in a very small number of deaths. A blood test of your kidney function may be done within the month before an MRI scan with gadolinium contrast. You will not receive gadolinium for a research MRI scan if your kidney function is not normal or if you received gadolinium within the previous month.

Most of the gadolinium contrast leaves the body in the urine. However, the FDA has issued a safety alert that indicates small amounts of gadolinium may remain in the body for months to years. The effects of the retained gadolinium are not clear. At this time, retained gadolinium has not been linked to health risks in people whose kidneys work well.

Some types of gadolinium contrast drugs are less likely to remain in the body than others. In this study, we will use the gadolinium contrast drugs that are less likely to remain in the body.

Please tell your research team if you have had any MRI scans in the past 12 months. We will also give you additional information called a "Medication Guide." Upon request, we will give you individual information about retained gadolinium we see on your studies.

What are the risks related to pregnancy?

You may not participate in this study if you are pregnant. If you are able to become pregnant, we will perform a pregnancy test before exposing you to radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

What are the risks of radiation from being in the study?

During your participation in screening for this research study, you will be exposed to radiation from a CT scan of the chest, abdomen and pelvis. The amount of radiation exposure you will receive from these procedures is equal to approximately 1.1 rem. A rem is a unit of absorbed radiation.

Every day, people are exposed to low levels of radiation that comes from the sun and the environment around them. The average person in the United States receives radiation exposure of 0.3 rem per year from these sources. This type of radiation is called "background radiation." No one knows for sure whether exposure to these low amounts of radiation is harmful to your body.

The CT scan that you get in this study will expose you to the roughly the same amount of radiation as 3.7 years' worth of background radiation. Most of the time, this amount of extra radiation is not harmful to you. However, scientists believe that being exposed to too much radiation can cause harmful side effects. This could include getting a new cancer. We estimate that this could happen in about 1 out of every 1000 people who get a very large amount of extra radiation.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, you may gain clinical information about your disease or your organ function that will be helpful to your overall medical care. This testing may show that you are eligible for the treatment trial for B-cell lymphoma.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could may choose not to be tested for eligibility or to have any other studies done.

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

All of the clinical test results will be shared with you. We will discuss any findings that are abnormal with you. We can also share the findings of these screening evaluations with any medical provider that you wish to have this information.

EARLY WITHDRAWAL FROM THE STUDY

You will be removed from the study if:

- You are found to be ineligible for the study

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding cancer, or 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.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

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

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and 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 that we will always be able to destroy your specimens and data. 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.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

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 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.

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

Your specimens and data may be stored by the NIH. When this study is closed, we will keep the samples for future research 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 that 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 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.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will not receive compensation for participation in this study.

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

On this study, the NCI will reimburse the cost for some of your expenses. Some of these costs may be paid directly by the NIH and some may be reimbursed after you have paid. The amount and form of these payments are determined by the NCI Travel and Lodging Reimbursement Policy. You will be given a summary of the policy which provides more information.

If your travel to the NIH Clinical Center (e.g., flight, hotel) is arranged and paid for by the NIH, the agency making the reservations and their representatives will have access to your identifiable information.

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.

- If some tests and procedures are performed outside the NIH Clinical Center, you may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the NIH Clinical Center.
- Once you have completed taking part in the study, medical care will no longer be provided by the NIH Clinical Center.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (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 following pharmaceutical collaborators are providing the following drugs for this study to NIH without charge:

- Gilead Sciences, Inc. is providing magrolimab
- AbbVie, Inc., manufactures venetoclax
- Genentech, Inc., is providing venetoclax and obinutuzumab

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested. However, there are some research partners not associated with the NIH working on this study who may receive payments or benefits, limited by the rules of their workplace.

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

Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify 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. 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, Center for Cancer Research, or their agent(s)
- Qualified representatives from Gilead Sciences, Inc., the pharmaceutical company who provides magrolimab.

- Qualified representatives from AbbVie, Inc., the pharmaceutical company who produces venetoclax.
- Qualified representatives from Genentech, Inc., the pharmaceutical company who provides venetoclax and obinutuzumab.

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, Mark Roschewski, M.D., Building 10, Room 4N115, Telephone: 240-760-6183. 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:

_____.