**PRINCIPAL INVESTIGATOR:** Christopher Melani, M.D.

**STUDY TITLE:** Phase 1/2 Study of VIP152, Venetoclax, and Prednisone (VVIP) in Relapsed/Refractory Lymphoid Malignancies

**STUDY SITE:** NIH Clinical Center

Cohort: Treatment - Affected Patient

Consent Version: 11/07/2024

## WHO DO YOU CONTACT ABOUT THIS STUDY?

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## 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 a blood cancer such as aggressive B-cell lymphoma or peripheral T-cell lymphoma (PTCL) that does not respond to treatment or returned after treatment.

The main purpose of this research study is to learn if it is safe to give individuals with these cancers the drug VIP152 in combination with venetoclax and prednisone (VVIP). We also hope to learn if this combination of drugs may work together to treat aggressive B-cell lymphomas and PTCL.

VIP152 is an "investigational drug," which means it is not approved by the U.S. Food and Drug Administration (FDA) for the treatment of any disease. Although venetoclax and prednisone have been approved by the FDA to be used either alone or in combination to treat types of lymphoma, the use and combination of the drugs in this study is investigational.

There are other drugs and treatments that may be used for your disease, and these can be prescribed by your regular cancer doctor if you are not in this study. These drugs all work in different ways in the body as compared to the study drugs and with different side effects. If you would prefer other drugs or treatments, such as alternative chemotherapy regimens, radiation therapy, single-agent targeted therapy, and/or approved forms of immunotherapy, you should consider not joining this study.

Prior to taking part in this study, we will find out if you meet the study criteria, which is called screening. If you are not, you will be taken off the study.

The screening portion will include checking your health history, taking a complete physical exam, performing blood and urine tests, scans of your heart, and a review of a biopsy sample. You also may have biopsy of your tumor if we need them for confirmation of your diagnosis.

If you meet criteria and decide to join this study, here are some of the most important things that you should know that will happen:

- In the first part of the study (phase 1 portion), we want to find out the highest dose of VIP152 and venetoclax that is safe to use with prednisone. We will test increasing doses of VIP152 and venetoclax in small groups of patients. We also want to find out what kind of side effects these medications might cause. After the first part is done, we will enroll additional patients in a second part of the study (phase 2 portion) to learn more about whether these study medications can shrink your tumor(s).
- The study drugs will be given as follows in cycles of 21 days each.
- You will take the following by mouth once a day:
  - Venetoclax on days 1-10 of each cycle.
  - Prednisone on days 1-10 of each cycle.
- VIP152 will be given by IV infusion (i.e., into a vein) on day 2 and 9 of each cycle. You will come to the NIH on days that you receive medications by IV. Pegfilgrastim (growth factor support) will be given to you (an injection under your skin- subcutaneous injection) on Day 11.
- You will continue these 21-day treatment cycles for as long as you are tolerating the medication well, your disease is not getting worse, and you would like to continue study therapy up to a maximum of 24 cycles of treatment. If you have aggressive B-cell lymphoma or PTLC and you have a complete response to treatment (no signs of any cancer), then you will stop after 12 cycles of treatment.
- If more than 6 months have passed since you stopped treatment and your disease comes back or gets worse, you may be able to be treated with more cycles of this treatment if your doctor thinks it is appropriate and you haven't received any other treatments for your cancer.
- You may experience side effects from taking part in this study. Some can be mild or very serious, temporary, long-lasting, or permanent, and may include death. Examples of some of the side effects that you may have include: changes in blood counts (such as low red or white cells), gastrointestinal (such diarrhea, nausea, vomiting), rashes, fatigue, and infections. Since this is the first time that these drugs are being administered together, there may be side effects that we cannot predict.
- You will be seen regularly during the study. You will have clinical, laboratory, and imaging tests to see how you are doing and to see if the treatment is having any effect on your disease. We will also collect required samples from you (including blood, and tumor biopsies) for both clinical and research purposes. We may also collect saliva or cheek swabs for research.
- After the study treatment has ended, you will need to be seen at the NIH Clinical Center or be seen by a local oncologist periodically for up to about 5 years to assess your health and to determine what impact, if any, the study drugs may have had on your disease and then annually as your doctor feels is appropriate. If your disease worsens, or you need to start a

new anti-cancer treatment, we will continue to follow-up with you by phone to see how you are doing until we complete the main research goals of the study.

- Because of the possibility of potential harm to an unborn child, if you can become pregnant or you can father a child and your partner is able to become pregnant you MUST use birth control from the time you start treatment, throughout therapy (including interruptions in therapy), and for 90 days after the last dose of study therapy.

We do not know what side effects you might have, and we cannot know if you may benefit from taking part in this study. The potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by cancer. If you do not benefit, this study and the results from our research may help others in the future.

You are free to stop participating in the trial at any time. If you decide to stop, the study doctor may ask you to agree to certain tests to make sure it is safe for you to stop.

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?

You are being asked to take part in this study because you have a blood cancer such as aggressive B-cell lymphoma or peripheral T-cell lymphoma (PTCL) that does not respond to treatment or returned after treatment.

In this research study, the goal is to learn if it is safe to give the drug VIP152 in combination with venetoclax and prednisone (VVIP) to treat individuals with your type of cancer. We also hope to learn if this combination of drugs may work together to treat aggressive B-cell lymphomas and PTCL.

VIP152 is an "investigational drug", which means it is not approved by the U.S. Food and Drug Administration (FDA) for the treatment of any disease. Although venetoclax and prednisone have been approved by the FDA to be used either alone or in combination to treat types of lymphoma, the use and combination of the drugs in this study is investigational.

- 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 blood cancers, 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.

- Prednisone is a standard agent, often referred to as a steroid, that is given together with other medications in many lymphoma regimens. It is also commonly given as a premedication to lessen or prevent infusion-related side effects from some treatments. It is not fully known how it works in combination with treatment but has been shown to increase cancer cell death in some blood cancers and will be used in this study.
- VIP152 is a type of drug called a kinase inhibitor. Kinases are proteins inside cells that help cells live and grow. The kinases inhibited or blocked by VIP152 inside the tumor cell may stop the growth of the tumor. It is possible that the study drug will kill cancer cells or stop them from growing.

**WHAT WILL HAPPEN DURING THE STUDY?**

**Before you begin the study**

We will perform tests and procedures to find out if you are able to participate. 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 exam: This will include taking your height, weight, vital signs (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.
- Standard blood and urine tests:
    - Tests to measure your liver, kidney, white blood cells, red blood cells and platelets, blood electrolytes and how well your blood clots
    - If you are an individual who is able to get pregnant and you are not already known to be pregnant, you will also have a pregnancy test done. This may be done by blood or urine test. You will not be able to participate if you are pregnant.
    - To check for Hepatitis B and C infection: As part of our study, we will test you for infection with Hepatitis B and C. We will tell you what the results mean and if you will require more frequent testing for Hepatitis B and need to take medicine to prevent Hepatitis B reactivation while on the study. If you need to take medicine, you will take one, such as entecavir, by mouth every day until 12 months after your last dose of study therapy.

  - To check for Epstein-Barr virus (EBV) infection, cytomegalovirus (CMV) infection, HTLV-1 (human T-lymphotropic virus) infection (PTCL only), and SARS-CoV-2 infection. The research team will discuss the results with you and whether you may participate in the study.
  - To check for HIV infection: 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
  - Tests routinely done in patients with your type of cancer to confirm the status of your disease (will differ depending on your disease)
  - We may also need to collect all of your urine over a 24-hour period depending on the results of your blood test
- Imaging to show all sites of disease, including
  - Computed tomography (CT) scan: The CT scanner is a donut-shaped machine that uses x-rays to make computer pictures of the inside of your body. During the procedure, you will need to lie still on a table inside the CT machine. The table will move you in and out of the machine during the scan, and you will be told to hold your breath. The scan itself will only take a few minutes, and the entire visit will take about 30 minutes.
  - 18F FDG PET(Positron Emission Tomography) /CT scan: The PET scanner is a donut-shaped machine that uses x-rays combined with a dose of a radioactive material (tracer) to make computer pictures showing the inside of your body. Before the scan, we will give you an injection (shot) of radioactive material into your arm. After the shot, you will need to wait for about 30 minutes for the material to be absorbed by your body. After 30 minutes, you'll lie on a narrow, padded table. We will position your body for the scan. The scan itself is painless and won't make much noise. During the scan, you will need to lie very still. The scan will take about another 30 minutes to complete.
  - <u>MRI (magnetic resonance imaging):</u> An MRI makes pictures of the inside of your body using strong magnets instead of x-ray energy. At the time of each scan, you will be asked to fill out a screening form to verify that it is safe for you to have the scan. You will also be asked to remove any metallic objects you are wearing (for example, watches, earrings, or piercings). We may ask you to change into a hospital gown. Then, you'll be asked to lie on a narrow bed that will move into the MRI scanner. The scanner is a long, narrow tube that is open at each end. Once you are comfortable, the table will be moved into the scanner. You will need to lie still on the table during the scan. The scan will take about 90 minutes to complete. You will hear normal "hammering" or clicking and squealing noises during the scan. We will give you earplugs or earmuffs to muffle the sound. You will be able to communicate with the technician running the scan the entire time. We will also give you an emergency button to squeeze at any time if you want the scan to stop.

- An electrocardiogram (EKG) of the heart will be done to check the electrical activity and the function of your heart
- An echocardiogram (ECHO) of the heart will be done to check how your heart's chambers and valves are pumping blood through your heart
- A sample of tissue from any previous surgery or biopsy will be tested at NCI to confirm your diagnosis, stage, and status of your disease. If no tissue is available, then a biopsy may need to be performed if you have accessible tumor site. Usually, tissue can be obtained safely and comfortably with local anesthesia. However, some participants may require conscious sedation. Conscious sedation is usually given to help someone relax and minimize discomfort. It can be given as a pill, a shot, an IV or even inhaled. You may have to wait up to an hour to start feeling the effects, depending on how it is given. Once it takes effect, you will be mostly awake, though relaxed or drowsy. We will monitor you throughout the procedure.

We will remove you from the study if the tests show you are unable to participate.

**VVIP Study Treatment**

You will be seen at the NIH at least every 3 weeks while on the treatment, and on Days 2 and 9 of every cycle to receive the VIP152 by intravenous (IV) infusion. A small plastic tube is put into a vein in your arm to give you the medication, or through an already installed central venous catheter (if it meets our requirements). You will be seen on day 15 of every cycle to have tests to assess your health.

Study treatment will be given in a series of cycles. Each cycle is 21 days (3 weeks).

In order to confirm the dose of VIP152 and venetoclax that is safe, patients will be enrolled and start study treatment in groups as follows:

- Phase 1: First, a group of 3-6 study participants will receive prednisone, at fixed doses together with VIP152 and venetoclax at the starting dose. The dose of VIP152 and venetoclax will be escalated (or increased) in a new group of 3-6 patients, as long as there were no safety issues in the first group. If there are no safety issues in the second group, the dose of VIP152 and venetoclax will be increased again in ongoing groups of 3-6 patients for as long as it is safe to do so, and until the best or highest dose of VIP152 and venetoclax planned for this study is found. Each group of participants will be monitored closely for side effects by the study staff for at least 3 weeks before enrolling the next group and/or moving on to the next doses.
- Phase 2: Once the highest safe dose of VIP152 and venetoclax given together with prednisone is found, then the next part of the study will begin. In this part of the study, participants will receive the safest doses of the study drugs as determined in the phase 1 part of the study to learn more about this drug combination and its effect on the treatment of agressive B-cell lymphoma and PTCL.

The treatment schedule for each study drug is described in more detail here:

- Venetoclax: This is an oral drug, taken by mouth once each day on days 1-10 of each cycle. Venetoclax tablets should be taken with a glass of water and should be taken with food. Do not break or chew the tablets.
- Prednisone: This is an oral drug, taken by mouth once each day on days 1-10 of each cycle. Prednisone tablets should be taken with a glass of water, with or without food. Do not break or chew the tablets.
- VIP152: This is a drug given by IV infusion on days 2 and 9 of each cycle.

All study participants will take the same doses of prednisone. Your dose of VIP152 and venetoclax will be assigned depending on what dose level is open at the time of your enrollment during phase or the safe dose found in phase 1 during the phase 2 portion. Pegfilgrastim (growth factor support) is a medication that helps to stimulate the growth of white blood cells and is used to decrease the incidence of infection. It will be given to you (an injection under your skin- subcutaneous injection) on Day 11.

You will receive a supply of each of the oral medications to take at home on the days you are not seen in the clinic. Each of the oral drugs should be taken at about the same time each day, with or without food as described above. If you do not remember to take all or any of the medications, do not make-up the dose or take extra the following day to make-up for the missed dose.

All medications should be stored at room temperature – not exposed to too high or low temperatures (that is, NOT in the refrigerator, freezer, bathroom, or in the car for a long period of time). You will be given a drug diary to help you remember the schedule and to record each dose that you take, if you choose to do so. We will ask you to bring this diary and any leftover supply of study medications to each clinic visit.

Certain medications and/or live vaccines, need to be used with caution or avoided all together while you are participating on this study. If any physician other than the study team prescribes a medication or vaccine for you for another condition, or you want to take any new over-the-counter medications, vitamins or herbal supplements, you must tell us and check with us prior to starting. This is important because the interaction of some medications may cause serious side effects and/or may still be unknown. You should also avoid grapefruit, grapefruit products, starfruit and Seville oranges as these may affect how your body processes the study medications. Your study team will discuss what medications to avoid during your study participation.

You will continue these 21-day treatment cycles for as long as you are handling the medication well, your disease is not getting worse, and you would like to continue study therapy for up to a maximum of 24 cycles of study treatment. If you have aggressive B-cell lymphoma or PTLC and you have a complete response to treatment (no signs of any cancer), then you will stop after 12 cycles of treatment.

**Study Procedures**

Similar to the tests done at the beginning of the study to determine eligibility, the following will be done to see how you are doing and how cancer may be responding to treatment:

<u>Clinical Assessments and Procedures:</u>

- History and physical exam, including obtaining information about how you function in your daily activities, side effects and symptoms, and a review of your medications: before starting treatment, before the start of every cycle, and at the end of treatment or when your disease gets worse
- Vital signs taken before starting treatment, before the start of every cycle, on Days 2 and 9 (when you receive VIP152 infusion), and at the end of treatment or when your disease gets worse
- Standard blood tests (approximately 2 tablespoons per visit): before starting treatment, before the start of every cycle, on Day 9 and 15 of every cycle, and at the end of treatment or when your disease gets worse (unless noted otherwise below):
    - Tests to measure your liver and kidney function, white blood cells, red blood cells and platelets, and blood electrolytes
    - If you can get pregnant and you are not already known to be pregnant, you will also have a pregnancy test done before starting treatments, and before the start of every cycle (this may be done by blood or urine test).
    - Tests routinely done in patients with your type of cancer to confirm the status of your disease- before starting treatment and before the start of every cycle (these may differ depending on the type of disease you have)
    - To check for cytomegalovirus (CMV)- before the start of every cycle, as this may be reactivated by your treatment if you've had this virus in the past
    - To check for Epstein-Barr virus (EBV)- before starting treatment, and before the start of every cycle, as this may be reactivated by your treatment if you've had this virus in the past
    - If you have hepatitis B infection that is not active, you will have additional monitoring for hepatitis while you are taking study drugs and for at least one year after your last dose of the study drugs.
- Imaging to show all sites of disease, including CT or MRI and 18F FDG PET/CT scans as follows:
    - CT scan of your neck, chest, abdomen and pelvis- before the start of Cycle 2, and then before the start of odd cycles and at the end of treatment or when your disease gets worse. An MRI may be done instead, depending on your disease type and if your doctor thinks it is a better imaging method for you, see below)
    - MRI may be done instead of CT scan
    - 18F FDG PET/CT scan- after Cycles 6 and 12, and at the end of treatment or when your disease gets worse.
- A bone marrow aspiration and/or biopsy will be done before starting treatment, after cycles 6 and 12 (if positive before starting treatment), and at the end of treatment or when your disease gets worse (as clinically indicated). 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.

**Additional research testing**

In addition to the tests that we will conduct to determine whether you are having side effects or if you are responding to the study therapy, we will also collect samples from you for purposes of research only. Some of these samples will be collected and stored for future use.

- Blood Samples:
  - Blood (about 3.2 tablespoons) will be collected: before starting treatment, Cycle 1 Day 11, at the start of every cycle, when your disease gets worse and during follow-up before your disease gets worse (not 30-day safety follow-up).
  - Pharmacokinetic (PK) blood samples (about 1 teaspoon each) collected to look at levels of some of the study drugs in the body. These samples will only be collected in some patients at the request of your study doctor. These samples would be done as follows:
    - Several times on day 2 of cycle 1, cycle 2 and cycle 4 (up to 24 hours after receiving study drug that day).
- Tissue Samples: If tissue from your original diagnosis and/or from a procedure for your disease is available (taken either before or during the study), this may also be collected for the study.
- Saliva or Cheek Swab Samples: Sometime after you start on the study and before your first dose of any study drug, a saliva sample or cheek swab sample will be collected for the study to allow us to look at your normal DNA. In some cases, this might also be done by a blood sample. We will collect this sample once at the beginning of the study.
- Biopsies:

  The biopsies are an optional part of the study and you will only be asked to have a biopsy if your doctors believes it to be safe. We will ask you to undergo a tumor biopsy at the beginning of the study, and again if your disease should come back or get worse during or after treatment on this study. The tissue is being collected for special research tests. Usually, tissue can be obtained safely and comfortably with local anesthesia. However, some participants may require conscious sedation. Conscious sedation is usually given to help someone relax and minimize discomfort. It can be given as a pill, a shot, an IV or even inhaled. You may have to wait up to an hour to start feeling the effects depending on how it is given. Once it takes effect, you will be mostly awake, though relaxed or drowsy. You will be monitored throughout the procedure. Biopsies will NOT be done on this study if they require general anesthesia. We may ask that you have ultrasound and/or CT scan to help clearly locate your tumor when doing a biopsy.

  Your doctor or the study team will discuss the biopsies with you. The optional biopsies to be performed are exclusively for research purposes and will not benefit you. They might help other people in the future.

  If at any time you do not want to have a biopsy done, please tell us. If you do not want the biopsy, this will not interfere in any way with your treatment. You will be asked to sign a separate clinical procedure consent form at the time of each optional biopsy.

A part of the tissue collected from the biopsy may be sent to the clinical laboratories for a standard of care evaluation to confirm the stage and grade of your disease. Portions of the samples will also be used for research tests.

The following sections describe studies to be done on your samples for research:

What tests will be done on my samples?

All of your samples collected for research purposes on this study (such as the tumor and normal tissue) may be used to check for levels of some of the study drugs in the body, to look at your body's immune response to treatment, and to look for specific changes in the DNA in tumors that could be used to develop new ways of diagnosing and treating cancer. DNA (also called deoxyribonucleic acid) contains information for making proteins and is passed from one generation of cells to the next. RNA (also called ribonucleic acid) uses information contained in DNA to tell the cell how to make proteins. Proteins perform many important functions in cells, tissues, and in the body and are a part of various structures, such as muscles, skin, and hair. Tumor cells contain DNA that has been mutated (or changed) so that the cells do not function normally. For example, in many types of cancer, tumors grow because cells in the tumor ignore signals from the body to stop dividing.

To study your DNA and RNA, we may do what is called "DNA and RNA sequencing." This is where we will do special tests in the lab to look at the sequence, or order, of the chemicals in your DNA and RNA. The sequence is what makes you biologically unique. No two human beings, except identical twins, have the same DNA sequence.

To determine which parts of the DNA and RNA have mutated, we will compare the DNA and RNA in your tumor cells to the DNA and RNA from normal cells. We will then analyze the results from similar tumors to see if there are any changes in the DNA and RNA that are common to a particular type of tumor.

To examine the tumor and normal tissue we may use several different techniques depending on the type of tissue we collect. These could include looking in detail at the parts of the genes (DNA sequences) that contain information to produce specific proteins.

However, you should know that the analyses that we perform in our laboratory are for research purposes only; they are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing or testing for routine clinical care. For these reasons, we will not give you the results of the research tests done on your research samples in most cases. There may be exceptions to what we share with you and this is described later in this consent form in the section for "Return of research results."

**When you are finished taking the drugs (treatment)**

When you finish taking the study treatment, you will be asked to return to the clinic or be seen by your local physician with result sent in, as soon as possible after end of treatment (within a day) and at about 30 days after the last dose of study drug. At these/this visit we will repeat most of the tests and procedures above and see how you are doing. We will continue to contact you more frequently after this visit if you continue to experience side effects from the medications.

After this visit, we will ask you to return to clinic or be seen by your local physician with results sent in, at about the following times after treatment for as long as your disease does not recur

(come back) or gets worse: every 3 months in year 1 post-treatment, every 4 months in year 2, every 6 months in year 3, and once each year in years 4 and 5. We may contact you by phone (or mail, email, etc.) more frequently between visits to see how you are doing. After 5 years, we may contact you to see how you are doing for the rest of your life.

If at any time your disease recurs (comes back) or gets worse, we will ask you to return to the clinic for one more visit to repeat some of the tests and procedures above, and to have an optional tumor biopsy (if safe to do so).

After the time that your disease gets worse, we will continue to contact you by phone (or mail, email, etc.) to see how you are doing every 6 months for the rest of your life.

**HOW LONG WILL THE STUDY TAKE?**

If you agree to take part in this study, your involvement is expected to last for at least 5 years. After this time, we may continue to contact you until we complete the main research goals of the study, which we expect will take 4-5 years.

**HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?**

We plan to have approximately 115 people get the study drugs at the NIH.

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

If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and will let you know if changes occur that may affect your health.

Here are important things to know about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.

- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

Risks and side effects related to the treatment and the procedures on this study are identified below:

**VIP152**

Likely:

- Nausea
- Vomiting
- Low white blood cell count (cells that help fight infection) (neutropenia)

Less Likely:

- Low red blood cell count (anemia)
- Diarrhea
- Fatigue (feeling tired)

**Venetoclax**

Likely:

- Low white blood cell count (cells that help fight infection) (neutropenia)
- Low red blood cell count (anemia)
- Low platelet count (cells that help blood to clot) (thrombocytopenia)
- Diarrhea
- Nausea
- Fatigue (feeling tired)
- Upper respiratory tract infection

Less Likely:

- Low white blood cell counts with fever (febrile neutropenia)
- Vomiting
- Constipation
- Fever (pyrexia)
- Swelling of the hands and feet (peripheral edema)
- Pneumonia
- Chemical imbalance in blood (including low potassium, high levels of uric acid, lactate dehydrogenase)
- Back pain
- Headache
- Cough
- Dizziness (syncope)

- Infection (including lower respiratory infection)
- Low levels of oxygen in the blood (hypoxia)

Rare but Serious:

- Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells, which may lead to changes in kidney function, abnormal heartbeat, or seizures (Tumor Lysis Syndrome)
- Liver failure (hepatic failure)
- Infertility in males
- Severe infection throughout the body (sepsis)

**Prednisone**

- Common side effects include: sleep problems (insomnia), mood changes, increased appetite (which may include gradual weight gain), acne, increased sweating, skin changes (including dry skin, thinning skin, bruising or discoloration), slow wound healing, headache, dizziness/spinning sensation, nausea, stomach pain, bloating, and changes in the shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist)
- Rare, but serious: Changes in vision, eye pain, severe changes in mood (such as depression or extreme happiness), bloody or tarry stools, coughing up blood, pancreatitis, very low potassium, and very high blood pressure.
- Some of these side effects are seen with prolonged and continued use of prednisone. Please contact the study staff if you are experiencing a side effect or think you might be having a severe reaction.

**Other risks from treatment**

- Allergic and infusion reactions: Sometimes people have allergic reactions to drugs. Serious allergic reactions can be life-threatening. If you have an allergic reaction, you might develop a rash, difficulty breathing, wheezing when you breathe, sudden low blood pressure with light-headedness, swelling around the mouth, throat or eyes, a racing heartbeat, and/or sweating. Before starting the study drug, you must tell your study doctor about any drug allergies. You should tell a member of the study team right away if you have any allergy symptoms listed above.
- Immunization: Please discuss with the study team prior to receiving any immunizations as receiving a live vaccine during or soon following treatment could result in side effects, or make them less effective.
- Infections:
  - You may experience viral, bacterial, or fungal infections during treatment, and this has been seen with treatment with the medications used in this study. Some of these infections have led to hospitalization and death. Contact your study doctor immediately if you have fever, chills, weakness, confusion, body aches, cold or flu

symptoms, feel tired or feel short of breath – they could be signs of an infection or any other signs or symptoms of a possible infection.

- Hepatitis:
  - In patients with a history of hepatitis B infection, treatment on study could cause it to return. You should not receive any of the study medications if you have active hepatitis B or C liver disease. If you have had hepatitis in the past we will monitor you during the study. You should tell your study doctor immediately if you have any of these symptoms which may suggest hepatitis: worsening of fatigue and yellow discoloration of the skin or eyes.
- Medication interactions:
  - If any physician other than the study team prescribes medication for you for another condition, or you want to take any new over-the-counter medications, vitamins, herbal supplements, or other, you must tell us and check with us prior to starting in most cases. This is important because the interaction of some medications may cause serious side effects and/or may still be unknown.
  - You should also avoid grapefruit, grapefruit products, Seville oranges, and starfruit as these may affect how your body processes the study medications.
- Secondary cancers: Patients with cancer have a higher risk of developing another or second new cancer when compared to people without cancer. These include solid tumors, skin cancer, and cancers of the blood. Participants should make their doctors aware of their medical history and any concerns they may have regarding their own increased risk of other cancers. The study team will be checking you for any possible new cancers that may develop during or following your treatment
- Sunlight Exposure: Avoid direct exposure to sunlight due to the ultraviolet absorption properties of VIP152.

**Risks from tests and procedures**

- Blood draws: The possible side effects of drawing blood include pain, bleeding, bruising, dizziness, light-headedness, fainting and, on rare occasions, local blood clot formation or infection with redness and irritation of the vein. The maximum amount of blood that will be drawn at a single timepoint on study is approximately 6.4 tablespoons. The maximum amount of blood that will be drawn over 8 weeks on the study is approximately 42 tablespoons.
- Tumor biopsy: The likely side effects include discomfort or pain, redness, swelling, and/or bruising at the site of the needle insertion. Bleeding from the site of the needle insertion is a less likely risk. Rarely, significant infection or bleeding from this procedure, allergic reaction to the anesthetic, or formation of a scar at the site of needle entry occurs. If you will have sedation with the procedure, the most common risks of conscious sedation last up to a few hours after being given can include drowsiness, feeling slow or sluggish, low blood pressure, headache, and nausea.

- Bone marrow: A numbing agent that can cause a stinging or burning sensation may be injected at the site of your bone marrow biopsy. The biopsy needle will go through the skin into the bone and may produce a brief, sharp pain. As the bone marrow liquid is taken from the bone, there may be a brief, sharp pain. Since the inside of the bone cannot be numbed, this procedure may cause some discomfort, however not all patients experience discomfort. The possible side effects associated with a bone marrow biopsy include pain, bleeding, bruising, and infection, as well as a reaction to the numbing agent.
- Imaging:
    - CT and PET Scan: If contrast dye is used, there is a risk for allergic reaction to the dye. Participants might experience hives, itching, headache, difficulty breathing, increased heart rate, and swelling. If you are allergic to or sensitive to medications, contrast dye, iodine, or shellfish, please notify your study doctor. If you have had kidney failure or other kidney problems in the past, please notify your study doctor.
    - MRI

      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.
    - Risks for gadolinium enhanced MRI scans:

      **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.

      **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 happen in less than 1% of people who get it. Symptoms usually go away quickly. Mild symptoms may include:

        - your arm being cold during the injection,

- a metallic taste,
- headache, and
- nausea.

More severe symptoms have been reported in an extremely small number of people (fewer than 1 in 300,000 people). These symptoms include:

- shortness of breath,
- wheezing,
- hives, and
- lowering of blood pressure.

You should not get gadolinium if you ever had an allergic reaction to it. We will ask you about any allergic reactions before giving you gadolinium.

People with kidney disease are at risk for a serious reaction to gadolinium contrast called "nephrogenic systemic fibrosis (NSF)." NSF always involves the skin and can also involve the muscles, joints, and internal organs. NSF has resulted in a very small number of deaths. We may do a blood test of your kidney function within 30 days before an MRI scan with gadolinium contrast. You will not get gadolinium for a research MRI scan if your kidney function is below the safe level.

Most of the gadolinium contrast will leave your body in the urine. However, the FDA has issued a safety alert that says small amounts of gadolinium may stay in your body for months or years. The long-term effects of the gadolinium that stays in your body are unknown. Some types of gadolinium are less likely to remain in the body than others. In this study, we will use the gadolinium contrast that is less likely to remain in your body, whenever we can. We will also give you additional information called a "Medication Guide." If you ask, we will also give you individual information about any remaining gadolinium we see on your scans.

**What are the risks related to pregnancy?**

If you are able to become pregnant, we will ask you to have a pregnancy test before starting this study. You must use effective birth control methods and try not to become pregnant during study treatment, and for 90 days after you finish study treatment. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the study team as soon as possible. If you plan to become pregnant in the future, please discuss with the study team how long you need to wait before becoming pregnant after completing the study.

If you are a sexually active person with a partner able to become pregnant, it is important that your partner not become pregnant during study treatment, and for 90 days after you finish study treatment. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your

partner has become pregnant during your participation in this study, please contact the study team as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

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

During your participation in this research study, you will be exposed to radiation from up to ten CT scans of the neck, chest, abdomen and pelvis, three FDG PET scans, and two CT-guided biopsies. The amount of radiation exposure you will receive from these procedures is equal to 18.2 rem. A rem is a unit of absorbed radiation.

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

The CT scans and $^{18}$F-FDG PET scans that you get in this study will expose you to roughly the same amount of radiation as 60.7 years' worth of background radiation. Being exposed to too much radiation can cause harmful side effects such as an increase in the risk of cancer. The risk depends on how much radiation you are exposed to. Please be aware that about 40 out of 100 people (40%) will get cancer during their lifetime, and 20 out of 100 (20%) will die from cancer. The risk of getting cancer from the radiation exposure in this study is 1.8 out of 100 (1.8%) and of getting a fatal cancer is 0.9 out of 100 (0.9%).

**Risk associated with return of genetic research results**

This study will involve genetic testing of your blood or tissue samples. In the unlikely event that we discover medically important genetic test results that we need to share with you, you and your family members may encounter some risks from receiving these results (see "Return of research results" below). Some of these risks include:

- **Psychological risks.** You could learn that you have increased genetic risks for another disease or disability, and this may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.
- **Family risks.** Although your genetic information is unique to you, you share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Therefore, genetic test results you receive could mean something about genetic risks your family members face and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your genetic test results with them.
- **Privacy risks.** It may be possible that law enforcement agencies or other legal entities could obtain your genetic information to identify you or your blood relatives. It is also possible that employers or insurers could obtain your genetic information to discriminate against you or your family members.

**Protections against misuse of genetic information**

This study involves genetic testing on samples. Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

## WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study.

However, the potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer.

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

In the future, other people might benefit from this study because the knowledge gained from this study may help others in the future who have cancer.

## WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether to be in this study, we will discuss the other options that are available to you. Instead of being in this study, you could:

- choose to be treated with radiation or with drugs already approved by the FDA for your disease
- choose to take part in a different study, if one is available
- choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

You should discuss with your doctor your other choices and their risks and benefits.

## 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**

The results of the standard tests performed as part of the research are available to you as part of your medical record.

In addition, when we are examining your DNA, it is possible that we could find changes in other parts of your DNA that are not related to this research. These are known as “incidental medical findings”. These might include:

- Changes in genes that are related to diseases other than cancer
- Changes in genes that are not known to cause any disease. These are known as normal variations.
- Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.

Since the analyses that we perform in our laboratory are not nearly as sensitive as the tests that are performed in a laboratory that is certified to perform genetic testing, the genetic changes that we find may or may not be valid. Therefore, we do not plan to inform you of all of the genetic results of testing on your tissue and blood that is performed in our research lab. However, in the unlikely event that we discover a finding that is believed to be medically important based on medical standards at the time that we first analyze your results, we will contact you. This could be many years in the future. We will ask you to have an extra tube of blood drawn to verify the findings we have seen in our lab. If the results are verified, you will be re-contacted and offered genetic counseling here at NIH (no charge) or referral to an outside genetic healthcare provider (at your expense) to discuss the results.

## EARLY WITHDRAWAL FROM THE STUDY

Your study doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease worsens or comes back during treatment
- if you have side effects from the treatment that your study doctor thinks are too severe
- if your study doctor has to delay your treatment for too long
- if you need treatment with a medication that is not permitted on the study
- if you become pregnant
- if new information shows that another treatment would be better for you
- if you do not follow the study rules
- if the study is stopped for any reason

In this case, you will be informed of the reason therapy is being stopped.

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.

## 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 lymphomas 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.

**Will your genomic data be shared outside of this study?**

Your genome consists of all the DNA in your cells. Genomic data includes information about all of your genes (i.e. genetic information) as well as information about other DNA sequences. As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

**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 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.

**PAYMENT**

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

You will not receive any payment for taking part in this study.

**REIMBURSEMENT**

**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 such as those for hotel, travel, and meals. 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.

## 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.

- 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 generally 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 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 are using VIP152 developed by Vincerx through a collaboration between your study team and the company. The company also provides financial support for this study

## CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

## 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 Vincerx, who produces VIP152

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.

**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, Christopher Melani, MD, christopher.melani@nih.gov, 240-760-6057. 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: _____.