PRINCIPAL INVESTIGATOR:	Mark Roschewski, M.D.
STUDY TITLE:	A Phase 2 Study of Response-Adapted Therapy with Copanlisib and Rituximab in Untreated Follicular Lymphoma
STUDY SITE:	NIH Clinical Center
Cohort:	*Affected patient - Screening*
Consent Version:	07/17/2023

WHO DO YOU CONTACT ABOUT THIS STUDY?

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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). Members of the study team will talk with you about the information described 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 needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers. Taking part in research at the NIH is your choice.

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?

The purpose of the screening portion of this study is to see if you are eligible to participate in the main study.

The purpose of the main study is to see if the study drug, copanlisib, in combination with rituximab is effective in slowing the growth of follicular lymphoma.

Copanlisib (Aliqopa®) has been shown to slow the growth of cancer cells and cause tumor cell death. It does this by inhibiting, or interfering, with several cell-signaling pathways that lymphoma cells use to grow. Rituximab (Rituxan®) is a type of drug called a "monoclonal antibody". It is believed that rituximab works by using the body's immune system to attack the cancer. Rituximab may work by attaching to the cancer cells (lymphocytes) and causing the cells to die or by signaling

your immune system to destroy the cancer cells.

Copanlisib is approved by the Food and Drug Administration (FDA) for treatment of follicular lymphoma that has relapsed (or progressed) after prior treatment. Rituximab is approved by the FDA for several types of Non-Hodgkin's lymphoma, including types of follicular lymphoma, both as a single agent or in combination with other chemotherapy. The use of these two drugs together for initial treatment in follicular lymphoma is considered experimental. The FDA is allowing us to use these drugs together in this study.

Other purposes of the main study include drawing blood and collecting tissue to measure certain "biomarkers." The purpose of drawing these samples to measure biomarkers is to find out if there are any disease-related markers that may help predict how patients respond to copanlisib and rituximab. We also hope to learn more about why patients respond differently to treatment.

WHY ARE YOU BEING ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this study because you have follicular lymphoma for which you have not received any prior treatment.

The portion of the study this consent form describes is the screening portion of the study. If you are not found to be eligible for the study, you will be removed and not able to continue to the treatment portion of the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 65 patients will be enrolled on this trial.

DESCRIPTION OF RESEARCH STUDY PROCEDURES AND TESTS

Before receiving study therapy on the main portion of this study, you will have several tests performed to check whether the trial is suitable for you. This is called screening.

Your doctor will review your medical history and the drugs that you are currently taking to determine whether you can participate in this trial. A small part of tumor tissue that was previously collected from you, will be used to confirm your diagnosis. Some of these tests or procedures are part of regular care and may be done even if you are not being considered to join the study. We will include results from all testing done as part of the research data. The following tests and procedures will be performed prior to starting treatment:

- Medical history: A complete review of your medical and cancer history, including obtaining information about your cancer diagnosis, and reviewing information about your other conditions.
- Physical examination: This will include height, weight, vital signs (temperature, blood pressure, heart rate, breathing rate), how you function in your daily activities, any current symptoms of your cancer and a review of all medications that you take.
- Blood/urine tests: We anticipate about 3 tablespoons of blood to be drawn during screening (likely less).
    - To check your blood counts, blood chemistries, blood clotting, blood sugars (hemoglobin A1C), viral studies (such as hepatitis B and C, HIV, CMV), to determine the health of your liver, for diagnosis and staging of your cancer

- 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
- Testing will also be done to check for Hepatitis B (HBV) and Hepatitis C (HCV) as giving the study medications to some patients with active hepatitis may not be safe. If you had a HBV infection in the past and it is no longer active, you may be allowed to be a part of this study but you will be monitored throughout to ensure that the amount of HBV in your blood (called viral load) stays low.
- Testing for cytomegalovirus (CMV) will be done before you start the study as giving copanlisib may reactivate the virus.
- For females of child-bearing potential, a pregnancy test will be done (urine or blood sample). You will not be able to participate if you are pregnant.
- A routine urine sample will be taken to check kidney function.

- Tissue review/biopsy: 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 taken. The biopsy may be done under sedation.
- Bone marrow testing: A bone marrow aspiration and/or biopsy will be done prior to starting treatment if not done within the last 12 months to confirm the stage and course of your disease. Bone marrow is the soft material in the center of bones that produces new blood cells. The area will be numbed with lidocaine and, once numb, a large needle will be inserted through a small cut to draw about 4 tablespoons of marrow out of the bone and to possibly remove a small piece of bone. Your level of pain will be monitored throughout the procedure and you'll be encouraged to voice any concerns. Additional numbing medicine may be utilized if necessary. The entire procedure will take about 1 hour to complete. We will call you about 2 days after the procedure to see how you are doing.
- Imaging: CT, PET, and MRI scans will be used to monitor your disease while you are on this study. The procedures for each type of imaging you may receive on study are outlined below:
  - CT scans: You will have a CT (Computed Tomography) scan performed as part of your screening procedures.

    The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures showing 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 instructed to hold your breath. The scan itself will only take a few minutes to complete, the entire visit will take about 30-90 minutes.

- [^{18}F] FDG PET/CT scans: You will have PET/CT (Positron Emission Tomography/Computed Tomography) scan performed as part of your screening procedures.

  The PET scanner is a doughnut-shaped machine that uses x-rays combined with a dose of a radioactive substance (tracer) to create computer pictures showing the inside of your body.

  Before the scan, you will have a radioactive substance injected into your arm after which, you will need to wait for approximately 30 minutes for the substance to be absorbed. We will place an intravenous catheter which is a small plastic tube inserted into a vein in your arm using a needle. After 30 minutes, you'll lie on a narrow, padded table and be positioned for the scan. The scan itself is painless and won't make much noise. During this time, you will need to lie very still. It will take about another 30 minutes to complete.
- MRI: As determined by your study doctor, you may have MRI (Magnetic Resonance Imaging) scans. An MRI creates 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 may be wearing (for example, watches, earrings or piercings) and possibly to change into a hospital gown. Then you'll be asked to lie on a narrow bed that will move into the MRI scanner. Before moving you into the scanner, special padding will be placed around your head to help keep your head still. Once you are comfortable, the table will be moved into the scanner (the scanner is a long, narrow tube that is open at each end). You will need to lie still on the table during the scan which will take about 30 minutes to complete. You will hear normal "hammering" or clicking and squealing noises during the scan. While in the scanner you will be fitted with earplugs or earmuffs to muffle the sound. You will be able to communicate with the technician running the scan the entire time and will be provided an emergency button to squeeze at any time if you decide you want the scan to stop.

  During part of the MRI you will receive gadolinium, a contrast agent, through an intravenous (IV) catheter (small tube). 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 OR DISCOMFORTS OF PARTICIPATION

The primary risks or discomforts of participating in this protocol are from complications caused by the screening 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.

Risks of procedures

- Blood Draws: Risks associated with drawing blood are slight, but some risks include pain, excessive bleeding, fainting or feeling lightheaded, bruising, infection (a slight risk any time the skin is broken), and multiple punctures to locate veins.
- Tumor Biopsy/Lymph Node Excision (if needed): 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, 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.). Conscious sedation and general anesthesia may be used if you find the risks acceptable. The risks for both are listed further below.
- Bone Marrow Aspiration and Biopsy: The bone marrow aspiration and biopsy may cause pain, bruising, bleeding and infection. Soreness near the site may last for a couple of days after the procedure. You may have more pain, risk of bleeding and bruising if you complete both aspiration and biopsy rather than just the aspiration. If your pain is severe or you develop a fever, please contact the study team immediately). Conscious sedation and general anesthesia may be used if you find the risks acceptable. The risks for both are listed below:

    - General Anesthesia: If you need to be sedated for a procedure it will be given by one of the NIH Clinical Center anesthesia specialists. Once the specialists evaluate you, they will discuss the risks of general anesthesia with you. You will be asked to sign a procedure and anesthesia consent.

      The anesthesia specialists will closely monitor your heart rate, blood pressure and breathing during the sedation. They may put a short plastic tube into your mouth to help keep the airway open. They may choose to use a breathing tube instead. They may give you oxygen to breathe while you are under general anesthesia.

      Although rare, any time a patient has general anesthesia there is a risk of a problem occurring. Most problems relate to decreased breathing rates. Using less anesthesia can fix this. Another risk is you can breathe stomach fluids into the lungs. This can result in an infection called pneumonia. We can treat the pneumonia with drugs such as antibiotics.

      People can have a bad reaction to sedative drugs. A severe reaction could include low blood pressure or heart rate problem. In this rare case, the anesthesia specialists may have to put a tube into your mouth and windpipe and use a respirator to breathe for you. They may give medication to increase your blood pressure. Some drugs may increase the chance of a seizure at first use. Please tell us if you or a family member had problems with general anesthesia.

    - Conscious Sedation: Alternatively, you may receive conscious sedation before undergoing a biopsy. 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 feel the effects depending on how it is given. Once it takes effect, you will be mostly awake, though relaxed or drowsy. The common side effects of conscious sedation include drowsiness, delayed reflexes, hypotension, headache, and nausea. These are generally mild and last no more than a few hours. You will be monitored throughout the procedure.

- Imaging:
  - CT scans and FDG PET/CT scans: CT and FDG PET/PET scans expose you to radiation; the amount of radiation you will be exposed to and the risks associated with this radiation are outlined in the section titled, "*What are the risks of radiation from research*?"

    The CT scans and FDG PET/CT scans will involve the use of a contrast agent. There is a chance of developing an allergic reaction from the contrast material, which may cause symptoms ranging from mild itching or a rash to severe difficulty breathing, shock or rarely, death. The contrast material may also cause kidney problems. The study doctors will do a blood test prior to the test to confirm that it is safe you to receive the contrast.

    For IV contrast: You may feel discomfort when the contrast material is injected. You may feel warm, flushed, get a metallic taste in your mouth or, rarely, may make you vomit or feel sick to your stomach. For oral contrast: you may experience vomiting, nausea, cramping, bloating, constipation or diarrhea after drinking the contrast.

    The risks of IV insertion include temporary pain and bleeding or bruising at the site where the IV enters the skin. In placing the IV, there is a small chance of fluid leaking into the tissue surrounding the IV and infection, which may cause some swelling and discomfort. Rarely, the IV site may become infected, which might require treatment with antibiotics.

  - 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.

- Additional risks associated with gadolinium enhanced MRI: 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 (NSF)". This condition always involves the skin and can also involve the muscles, joints and internal organs. NSF 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 below the safe level.

  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. 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 research?

During your participation in the screening portion of this research study, you will be exposed to radiation from a CT guided biopsy if needed at screening, a CT scan to evaluate your disease and

an [^{18}F] FDG PET/CT scan. The amount of radiation exposure you will receive from these screening procedures is equal to approximately 3.3 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." 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/CT scan that you get in the screening portion of this study will expose you to the roughly the same amount of radiation as 11 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.

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.

POTENTIAL BENEFITS OF PARTICIPATION

Although there may be no direct benefit to you for participating in this screening portion of the study, it will determine whether you are eligible to participate in research studies in the NIH. You will also have the benefit of a consultation with one of the NIH doctors to discuss your treatment, and, if you so desire, the results of these screening tests and procedures will be communicated to your personal physician.

ALTERNATIVE APPROACHES OR TREATMENTS

What other choices do I have if I do not take part in this study?

Alternatives to participation in this protocol include receiving care and follow-up from your personal physician.

STOPPING PARTICIPATION

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

- if he/she believes that it is in your best interest
- if new information shows that another treatment would be better for you
- if you are found to be ineligible for the main study

In this case, you will be informed of the reason your participation 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 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. However, according to FDA guidelines, information collected on you up to that point may still be provided to Bayer or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have

been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases cannot be recalled and destroyed

CONFLICT OF INTEREST

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 but they do not need to report their personal finances to the NIH.

The National Institutes of Health and the research team for this study are using copanlisib, developed by Bayer through a joint study with your researchers and the company. The company also provides financial support for this study.

USE OF SPECIMENS AND DATA FOR FUTURE RESEARCH

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that they may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

If you do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

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.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We 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, NCI, or their agents.
- Qualified representatives from Bayer Pharmaceuticals, the pharmaceutical company who produces Copanlisib.

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 records 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 medical 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., at mark.roschewski@nih.gov or 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: _____.