PRINCIPAL INVESTIGATOR: David S. Schrump, MD

STUDY TITLE: Phase I/II Evaluation of Continuous 24h Intravenous Infusion of Mithramycin, an Inhibitor of Cancer Stem Cell Signaling, in Patients with Primary Thoracic Malignancies or Carcinomas, Sarcomas or Germ Cell Neoplasms with Pleuropulmonary Metastases

STUDY SITE: NIH Clinical Center

Cohort: Affected Patient

Consent Version: 12/22/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

David S. Schrump, MD, by phone at 240-760-6239 or email at schrumpd@mail.nih.gov

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.

If the individual being asked to participate in this research study is not able to give consent to be in this study, you are being asked to give permission for this person as their decision-maker. The term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research, throughout the remainder of this document.

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 this study is to find the highest safe dose of an experimental agent, called mithramycin that can be given to patients with tumors in the lungs, esophagus, pleura or mediastinum who have a certain genetic profile over a period of 24 hours instead of spread out over a longer period of time. Once we determine the highest safe dose, it will be tested on

additional subjects with these diseases to help us determine whether mithramycin delivered as a 24 hour infusion can cause tumors in lungs, esophagus, pleura, or mediastinum to shrink.

Mithramycin is drug which was tested and approved as an anti-cancer therapy in the 1960's and was found to have activity (shrink some tumors) against some forms of cancer. It was approved, but was never broadly accepted as a treatment due to serious side effects. Mithramycin is considered experimental in this study because it has not been approved by the US Food and Drug Administration (FDA) for treatment of your type of cancer. Because of its prior activity, researchers have continued laboratory research on the ability of mithramycin to fight specific cancers. In the laboratory mithramycin is active against cancers of the chest, including lung and esophageal cancer and mesothelioma.

During a recent study of mithramycin at the NCI, subjects with the diseases under study received mithramycin for 6 hours a day for 7 days in a row. In this study, we discovered that many patients were unable to receive higher doses of mithramycin because of a side effect of liver damage. Further investigation revealed that only subjects that possessed certain forms of genes suffered the liver related side effects. Therefore, we are limiting the persons who can enroll on this study to those who do not possess the genes that are associated with liver side-effects.

Please note that in the current study, patients continued to experience temporary, reversible liver damage at the first dose we explored. Therefore, we have lowered all of the doses we plan to test on this study.

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

You are being asked to take part in this study because you have a cancer that affects the organs in your chest that is not shrinking with known effective therapies. In addition, you have certain genetic characteristics that will limit the chance that you will develop liver damage from mithramycin while on this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 60 persons will take part in this study.

DESCRIPTION OF RESEARCH STUDY

Before you begin the study

Before you begin this study, we will review your medical records and imaging studies to determine if you are eligible for this study. We will ask you questions over the telephone, other NIH approved remote platforms or in person about your medical history.

You will need to have certain studies done in order to determine whether you meet the criteria to participate in this study. Any tests or procedures done specifically to evaluate if you are eligible for this study will be explained to you by your doctor under a separate protocol (06C0014, "Prospective Evaluation of Genetic and Epigenetic Alterations in Patients with Thoracic Malignancies").

A pregnancy test will also be performed if you are a female who is capable of having children.

You will not be allowed to participate if we find that you are not eligible.

During the study

Prior to Starting Treatment

Prior to starting treatment, you may have the following tests and/or procedures in order for us to determine the extent of your disease right before your study treatment begins:

- A medical history
- Physical exam including vital signs
- Routine blood and urine tests
- Pregnancy test (if you are a woman who could have children)
- Tests that check the function of your lungs called PFTs (if necessary)
- CT, PET/CT and brain MRI scans
- An ultrasound study of your liver
- Research labs (~3 tablespoons)
- A tissue biopsy (if enough tissue was not able to be obtained from an earlier surgery or biopsy you may have had)

Study Therapy

If the exams, tests and procedures show that you can be in the study, and you choose to take part, you will be admitted to the hospital at NIH and given mithramycin intravenously (IV) over about 24 hours. IV drugs on this study will be given through a "central line", a catheter (or tube) that is surgically inserted into one of the main blood vessels in the arm or in your chest leading to your heart. The catheter may be tunneled under your skin and come out of your skin through a second small incision. We usually remove the catheter after each cycle but on occasion it can be left in for several cycles.

If you do not have unacceptable side effects or worsening of your cancer, this treatment can be repeated every 14 days. This is called a cycle. You will have to stay overnight in the hospital for each infusion.

The first 3 patients on this study were enrolled in the first part of the study (Phase 1), but had side effects we consider unacceptable. Therefore, the dose at which the next group of 3-6 patients enrolled will be reduced. If that dose is found to be tolerable, we will continue to test increasing doses until a dose is reached at which 2 or more patients have an intolerable side effect. We will select the next lower dose at which no more than 1 person out of 6 has intolerable side effects as the maximum tolerated dose (MTD). If we reach the highest dose level we plan to test with no more than one patient in each of the prior dose levels experiencing intolerable side effects, the highest planned dose will be named the MTD once 6 subjects have been treated at that level with no more than 1 having intolerable side effects.

The second part of the study (Phase 2) will begin after an MTD has been determined. Every patient enrolling in the second part of the study will receive the study drug at the MTD.

Safety and Treatment Evaluation Assessments

While you are receiving cycles of mithramycin, you will be watched closely for any adverse effects. You will need to have the following procedures and tests:

- Physical exam prior to receiving study drug in each cycle.

- Blood tests daily on the first 5 days and twice in the second week for the first cycle (less often for subsequent cycles).
- EKG on Days 1-5 of the first cycle (Days 1 and 2 for subsequent cycles).
- Scans to evaluate your tumor, described in the section titled "Research Assessments" below.

Research Assessments

Pharmacokinetic Studies (PKs)

Blood samples will be obtained from you to see how much of the mithramycin is in your blood (pharmacokinetics). These samples are about ½ teaspoon of blood each (~1/2 tablespoon total) and will be taken in Cycles 1 and 2 before the drug begins and near the end of the infusion. In Cycle 1 only, additional samples (~2 tablespoons total) will be taken at 2, 8 and 16 hours during the infusion and up to 8 samples will be taken periodically for up to 12 hours after the infusion has ended.

If we need to increase or decrease the dose of mithramycin you are given, we may obtain additional blood samples like during Cycle 1 above.

Additional Research Blood Samples

- On Day 1 and Day 4 of Cycle 1 and on Day 1 of every cycle, blood (~3 tablespoons) will be collected in order to conduct research studies.
- On Day 1 of Cycles 1 and 2 blood (~less than a teaspoon) will be collected and stored in case it is later needed to help us determine your clinical status at these times.

Scans

- CT, PET/CT and brain MRI scans to evaluate your tumor will be done after the end of each treatment course (every 4 cycles, ~8 weeks).
- Ultrasound study of your liver on Days 1 and 4 of Cycle 1 then on Day 1 of subsequent cycles. This study will also be done each time you have scans to evaluate your tumor (every 4 cycles).

Biopsy of Tumor Tissue

You will be required to have 2 biopsies of tumor tissue in order to participate in the study. These will be performed prior to starting treatment and on Day 4 of Cycle 1 to evaluate the effect of mithramycin on your tumor tissue. If you have sufficient tissue available from a biopsy performed earlier at NIH or elsewhere, you may not need to have the biopsy prior to starting treatment. A CT scan may be required to safely perform each tumor biopsy.

We may request additional optional biopsies: after you have completed 1 course (4 cycles) of therapy, as well as if you have improvement in your disease. These optional biopsies may be requested only if the tumor sample can be easily obtained and the study doctor determines that the biopsy would not be more risk to you than usual. These optional biopsies are not required for your participation in the study. You will be asked at the time of the procedure whether you would like to give us permission to obtain these additional samples.

Trained personnel will perform these biopsies. If any complication occurs, we will offer medical care. If upon attempting the first biopsy procedure, no tissue can be obtained or it has caused you harm, the second biopsy procedure will not be done. After you are enrolled in this study, if for any reason the biopsies cannot be done safely, you can still receive the study drugs but the biopsies will not be performed.

When you are finished taking the drugs

Once the mithramycin is stopped, you will need to come back to NIH or see your local physician weekly for evaluation (physical exam and blood work) until you recover from any side effects.

If your disease has remained stable or improved during the course of the study, you will also be seen here at NIH or by your local physician every two months for further blood tests and imaging studies (CT, PET/CT and MRI scans) of your tumor.

BIRTH CONTROL

If you are a woman who is breast feeding or pregnant, you may not take part in the study because mithramycin is known to cause birth defects and it is unknown whether or how a breastfeeding child might be affected by this investigational drug. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 2 months after you finish study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

RISKS OR DISCOMFORTS OF PARTICIPATION

You may have side effects while on the study. These may be caused by the study drug or the study procedures that you are asked to undergo. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the mithramycin. In some cases, side effects can be serious, long lasting, or may never go away. There is a risk of rare occurrence of death. We will tell you if we learn any new information that may affect your health, welfare, or decision to stay in this study. You should talk to your study doctor about any side effects that you have while taking part in the study.

Side Effects Associated with Mithramycin

Likely

- Decreased blood level of calcium

- Nausea or vomiting
- Diarrhea
- Loss of appetite
- Mouth sores
- Decreased platelets (the blood cell that helps blood clot)
- Decreased red blood cells (the blood cells that carry oxygen)
- Abnormal levels of white blood cells (the cells that prevent infection)
- Temporary increase in some liver function studies which should return to normal as soon as the drug is stopped

Less Likely

- Bleeding including nose bleed
- Fever
- Drowsiness
- Weakness
- Tiredness
- Pain, redness, soreness or swelling of the area where the IV goes in the skin
- Skin changes, blushing of the face
- Headache
- Mental depression, restlessness, irritability
- Muscle or stomach cramps, possibly due to a low blood level of calcium
- Abnormal levels of blood elements including phosphorus or potassium.
- Increase blood levels of liver enzymes, which may indicate damage to the liver
- Increased blood levels of kidney function tests, such as creatinine, urea or protein

Rare but Serious

- Bleeding that may require a transfusion of blood or blood products. Bleeding may result in bloody or black stools, or vomiting blood, or bloody nose, or small broken blood vessels under the skin.
- A significant rash called toxic epidermal necrolysis characterized by widespread and severe skin irritation has been reported with mithramycin.

While receiving mithramycin, you should avoid any drugs that contain salicylates, a component of aspirin, such as Aspirin, Bufferin, Ascriptin, Aspergum, Anacin, and some Alka-Seltzer products and some cold preparations, as they may increase the risk of bleeding.

When white blood cells are low (neutropenia), fever may be a sign of significant infection. When fever and neutropenia is present, hospitalization for administration of intravenous antibiotics may be necessary.

Because mithramycin may decrease the production of red blood cells (the part of the blood that carries oxygen and gives energy) and platelets (the part of the blood that helps prevent bleeding), it is possible that you will require transfusions with red blood cells or platelets. When these

transfusions are required will vary from participant to participant and can be discussed with your doctor. Most transfusions have no side effects. However, you may have an allergic reaction (a rash, hives or very rarely, difficulty breathing that can be so severe as to result in death). A separate informed consent will be obtained should you need a blood transfusion.

Side Effects Associated with Research Related Study Procedures

Blood Draw

Risks of blood sampling include pain and bleeding at the site where the blood is collected, lightheadedness, and rarely, fainting. When large amounts of blood are collected, low red blood cell count (anemia) can develop. Rarely, there is also a risk of infection at the needle site.

Urine Collection

There are no physical risks or discomforts associated with urine collection.

Ultrasound and Electrocardiogram (EKG)

These procedures are associated with minimal discomfort.

Pulmonary Function Tests

These tests are safe and side effects are unlikely, but may include brief light headedness or slight soreness of the chest.

Central Line

In order to receive this therapy you will need to have an intravenous catheter placed. This catheter is usually surgically inserted in the arm, chest or neck area into one of the main blood vessels leading to your heart. Central catheter placement is very common and is generally well tolerated. The catheter is necessary for infusion of chemotherapy on this study and for the drawing of blood. It is usually inserted under local anesthesia.

The risks associated with the procedure include pain, bleeding, infection, puncture of the underlying lung and pulmonary embolism. Lung puncture can result in lung collapse, which might require that a chest tube be placed into the chest cavity (usually for a day or two) to help the lung reinflate. The long-term risks of the catheter include infection and clotting of the vein in which the catheter sits, which can break off and travel to the veins near your neck, face, chest, arms or lungs (pulmonary embolism). If these occur, it may be necessary to remove the catheter. These risks will be explained to you in more detail at the time of the insertion.

Biopsy

Biopsies will be done using a small core needle under imaging guidance (CT, MRI, or ultrasound as deemed appropriate by the interventional radiologist performing the biopsy). Imaging helps the specialized radiologist know that the needle has been placed into the tumor mass. Typical risks of such procedures include, but are not limited to bleeding pain, and scarring at the biopsy site. Rarely, there is a risk of infection at the sampling site. If your biopsy is done under CT guidance, there will also be risks of radiation as described below.

Scans and Contrast

CT, PET and MRI scans are common standard imaging tests used in the diagnosis of cancer. The most common discomfort is the length of time a patient must lay still during a scan. Occasionally,

a patient may become uncomfortable with the closed space of the machines, particularly the MRI. If this occurs, your doctor can order a medicine to help you relax during this scan. If a contrast agent (the special dye) is given with the scan there is a small risk of having a reaction to the contrast. In that small group of patients who have a reaction, the most common symptoms are nausea, pain in the vein where the contrast was given, a metallic or bitter taste in the mouth, and a warm or flushing feeling that lasts from 1-3 minutes. Rarely do these symptoms require any treatment. In very rare cases, people have had severe reactions that affect their breathing and heart rhythm. If you have had a reaction in the past, be sure to tell you doctor or nurse about it.

An IV line may need to be inserted for administration of the contrast agent or anesthetic. This can cause pain at the site where the IV is placed and carries a small risk of bruising or infection.

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 6 CT scans, 6 PET/CT scans as well as a maximum of 5 CT-guided biopsies over the course of the first year. The amount of radiation exposure you will receive from these procedures is equal to approximately 17.8 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, PET/CT scans and CT-guided biopsies that you get in this study will expose you to roughly the same amount of radiation as 59.3 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%).

POTENTIAL BENEFITS OF PARTICIPATION

Are there benefits to taking part in this study?

The potential benefit of the treatment with mithramycin is that it may cause your cancer to stop growing or to shrink for a period of time. It may lessen the symptoms, such as pain, that are caused by the cancer. It is unlikely that this treatment will cure your cancer. Because there is not much information about the effect of mithramycin on the type of cancer that you have, we do not know if you will benefit from taking part in this study. Information learned from this study may help future patients with cancer.

ALTERNATIVE APPROACHES OR TREATMENTS

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

Instead of being in this study, you have these options**:**

- Getting treatment or care for your cancer without being in a study

- Taking part in another study
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

STOPPING THERAPY

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

- if he/she believes that it is in your best interest
- if you become pregnant during the study
- if your disease comes back during treatment
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

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 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. 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 can**not** 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 Protocol Review Guide. You may ask your research team for a copy of the Protocol Review 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.

Members of the research team working on this study may have up to $15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

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 just 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?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

On this study, the NCI will cover 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. Someone will work with you to provide more 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

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

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, David S. Schrump, MD, schrumpd@mail.nih.gov, 240-760-6239. 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

Legally Authorized Representative (LAR) for an Adult Unable to Consent: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

Signature of LAR	Print Name of LAR	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

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: _____.