**PRINCIPAL INVESTIGATOR:** **Arun Rajan, MD**

**STUDY TITLE:** **A Phase II Study of Sunitinib in Patients with Advanced Relapsed or Refractory Thymoma or Thymic Carcinoma with at Least One Prior Line of Platinum-Based Systemic Chemotherapy**

**STUDY SITE:** **NIH Clinical Center**

Cohort: Standard – Group 1

Consent Version: April 30, 2020

## WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Arun Rajan, MD
Phone: 240-760-6236
Email: rajana@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 evaluate the safety, tolerability and effectiveness of the drug sunitinib malate (referred to as sunitinib) in cancers of the thymus. Sunitinib is a Food and Drug Administration (FDA) approved drug for use in at least three other types of cancers including

cancers of the kidney, but it is not FDA approved for treatment of thymomas or thymic carcinomas and is experimental in this setting. Sunitinib acts by blocking several proteins involved in control of cell division and growth. In tumor cells such controls are altered and lead to abnormal and uncontrolled cell growth. Some of the proteins which are blocked by sunitinib are known to be abnormal in a few patients with cancers of the thymus. There have also been isolated reports of effectiveness of sunitinib in cancers of thymus.

This study will evaluate the amount of tumor reduction, if any, and the length of time the tumor growth is controlled, as well as the safety and tolerability of sunitinib in advanced cancers of thymus, which have progressed despite at least one prior chemotherapy regimen containing platinum. Some patients may not have any tumor reduction or control of tumor growth with sunitinib.

**Why are you being asked to take part in this study?**

You are being asked to take part in this study because you have an advanced thymoma or thymic carcinoma which has progressed despite prior treatment with at least one platinum-based chemotherapy regimen.

**How many people will take part in this study?**

This study is being conducted at the National Cancer Institute and affiliated institutions, and it consists of two groups. You are participating in Group 1, and enrollment has now been completed for that group. A total of 41 people with thymoma or thymic carcinoma enrolled in Group 1. In Group 2, approximately 15 patients with thymic carcinoma will take part in the study.

**DESCRIPTION OF RESEARCH STUDY**

This study is being conducted on an outpatient basis. Sunitinib is taken orally once a day, in the morning, with or without food. Sunitinib is stored at room temperature. The dose regimen for this study is 50 mg of sunitinib daily for 4 weeks, followed by 2 weeks of rest with no sunitinib. This 6-week period is called a cycle. The cycles may be repeated as long as you are receiving benefit from the drug and any side effects which you may experience are tolerable.

Clinic visits will take place every three weeks in order to monitor your progress on this trial and manage any side effects which you may be having. Every cycle (6 weeks) we will perform a CT scan, MRI and/or chest x-ray to see if you are getting any benefit from the study drug. As long as you are receiving benefits from the treatment and you do not have unacceptable side effects, then we will continue to provide you with the treatment. Once you have completed one year of the study drug, we will perform a CT scan, MRI and/or chest x-ray every 2 cycles (12 weeks) to see if you continue to receive benefits from the study drug. Once you stop getting any benefit from the study drug, or the side effects are no longer tolerable, we will stop the treatment.

**What will happen if you take part in this research study?**

**Before you begin the study**

Before any study-related procedures are performed, you will be asked to read and sign this informed consent form. If you wish to participate, you agree to return to this clinic for all study-related appointments and tests mentioned below. Additional visits may be required to treat side

effects. No overnight hospital or clinic stays are required; however, if serious side effects occur, overnight hospital stays may be required to treat the side effects.

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Routine physical exam (includes an examination of major body systems, height, weight, blood pressure, and pulse rate)
- Documentation of all prescription and over-the-counter medications which you are taking
- Blood tests including blood cell counts, chemistries, tests to see how well your blood clots and thyroid functions
- Computed tomography (CT) or MRI and/or chest x-ray (CT- a series of x-rays will be passed through your body while you lie inside a machine) or other imaging tests to locate and measure your tumors
- Tissue block of the cancer to submit to the study doctor or a member of the research team
- An electrocardiogram (ECG), a recording of the electrical activity of your heart
- An echocardiogram or MUGA scan, an ultrasound study which shows the structure and function of your heart
- Serum pregnancy test for women of childbearing age

**During the study**

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures that are part of regular cancer care:

- Clinic visits to discuss any symptoms you may have and to undergo a physical examination. During the first cycle, clinic visits are scheduled for Weeks 1 and 3. After the first cycle, clinic visits may be changed to once every 6 weeks, on Week 1 of each cycle, at the discretion of your study doctor.
- Blood tests
- Computed tomography or other imaging test approximately every 6 weeks for the first year you receive the study medication, and approximately every 12 weeks thereafter, as long as you continue to receive the study medication.
- Tests to monitor your heart function, as needed

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body and your cancer:

- Blood test to study different biological markers that we anticipate may be affected after treatment with sunitinib
- Blood test to evaluate the effect of the study drug on cells involved in specialized functions such as blood vessel formation.

You will be asked to maintain a medication diary and a blood pressure (BP) chart.

**When you are finished taking the study drug (sunitinib malate)**

As explained in the paragraphs above, if you do not experience benefit from the sunitinib, or the side effects are no longer tolerable, then we will stop giving you the sunitinib. We will continue to monitor you, either by clinic visit or telephone interview, until all of the side effects have been resolved or stabilized, and then annually until death.

**Study Chart**

| Day | What you do |
|---|---|
| Before starting study | • Check-in to the Outpatient Clinic<br>• Physical examination by a Health Care Provider<br>• Blood Pressure (BP) measurement<br>• Routine blood tests<br>• Research blood tests<br>• Tissue block of the cancer to confirm the diagnosis<br>• CT or other imaging studies<br>• ECG<br>• Echocardiogram<br>• Serum pregnancy test for women of childbearing age |
| During treatment | • Sunitinib 50 mg daily for 4 weeks, then 2 weeks of rest with no sunitinib<br>• Clinic visits during Cycle 1 on Weeks 1 and 3, including physical examination by a Health Care Provider, and other tests as determined by your study doctor. After the first cycle, clinic visits may be changed to once every 6 weeks, on Week 1 of each cycle, at the discretion of your study doctor.<br>• Research blood tests on Week 1 of Cycles 2 and 3<br>• CT or other imaging studies every 6 weeks for the first year you receive the study medication, and every 12 weeks thereafter, as long as you continue to receive the study medication.<br>• Routine blood tests on Weeks 1 and 3 for Cycle 1; then on Week 1 for Cycle 2 and after<br>• Maintain a medication diary<br>• Maintain a BP diary with weekly BP recordings. CT or other imaging studies every 6 weeks for the first year you receive the study medication, and every 12 weeks thereafter, as long as you continue to receive the study medication.<br>• Routine blood tests on Weeks 1 and 3 for Cycle 1; then on Week 1 for Cycle 2 and after<br>• Maintain a medication diary<br>• Maintain a BP diary with weekly BP recordings. |
| After treatment | • Follow-up clinic visits or telephone interviews until side effects are resolved or stabilized, and then annually until death. |

**Study Drug Administration**

Sunitinib is taken orally once a day, in the morning, with or without food. Sunitinib is stored at room temperature. The dose regimen for this study is 50 mg of sunitinib daily for 4 weeks, followed by 2 weeks of no sunitinib. This 6-week period is called a cycle. After 12 weeks of treatment, we will perform a CT scan to see if you are getting any benefit from the treatment. If you do not experience benefit from sunitinib, we will stop it. If you experience benefit from sunitinib, we will continue it until you stop benefiting from it and do not have unacceptable side effects. We would like to follow up with you even after you stop taking sunitinib; for your entire life with the intention of knowing more about how the genetic characteristics of your cancer have an impact on how your cancer behaves.

**Study Restrictions/Subject Responsibilities**

- Store sunitinib at controlled room temperature (15to 30$^{o}$ C), and protect from light.
- Sunitinib may be taken without regard to meals in the morning.
- A yellow discoloration of the skin area may result following direct contact with the capsules. Wash the exposed area with soap and water immediately.
- Blood pressure (BP) should be monitored before you begin the study, and then weekly for the duration of treatment. Blood pressure may be monitored either at the doctor's office or using any calibrated electronic device (such as those found at a local drug store or pharmacy).

Sunitinib may interact with many other medications and remedies. We would like to know all the medications that you take before starting sunitinib as well as any new medications and over the counter drugs. We will provide you information sheet describing drugs, remedies, and medications with potential interactions with sunitinib.

**BIRTH CONTROL**

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how these medicines used in this study would affect your baby or your unborn child. 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 and while receiving study treatment. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once. It is also important to note that some of the drugs used in the study may make you unable to have children in the future.

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

**What side effects or risks can I expect from being in this study?**

If you choose to take part in this study, there is a risk that sunitinib malate (SU011248 L-malate) 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 sunitinib malate (SU011248 L-malate) 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.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points 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, or 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.

The table below shows the most common and the most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

**Sunitinib Risks**

| **COMMON, SOME MAY BE SERIOUS**<br>In 100 people receiving sunitinib malate (SU011248 L-malate), more than 20 and up to 100 may have: |
|---|
| • Pain<br>• Constipation, diarrhea, heartburn, nausea, vomiting<br>• Sores in the mouth<br>• Tiredness<br>• Loss of appetite<br>• Changes in taste<br>• Sore throat<br>• Redness, pain or peeling of palms and soles |

| **OCCASIONAL, SOME MAY BE SERIOUS**<br>In 100 people receiving sunitinib malate (SU011248 L-malate), from 4 to 20 may have: |
|---|
| • Anemia which may require blood transfusion<br>• Blurred vision with chance of blindness<br>• Bloating, passing gas<br>• Dry mouth, skin<br>• Chills, fever<br>• Swelling of arms, legs<br>• Flu-like symptoms including body aches<br>• Bruising, bleeding<br>• Weight loss<br>• Infection, especially when white blood cell count is low<br>• Dehydration<br>• Dizziness, headache<br>• Feeling of "pins and needles" in arms and legs<br>• Depression<br>• Difficulty sleeping<br>• Cough, shortness of breath<br>• Nose bleed<br>• Hair loss, rash, itching, skin changes<br>• Change in hair color<br>• High blood pressure which may cause headaches, dizziness, blurred vision |

| **RARE, AND SERIOUS**<br>In 100 people receiving sunitinib malate (SU011248 L-malate), 3 or fewer may have: |
|---|
| • Anemia, kidney problems which may cause tiredness, bruising, swelling, or may require dialysis<br>• Blood clot which may cause confusion, paralysis, seizures or swelling, pain, shortness of breath<br>• Damage to organs (heart, brain, others) which may cause shortness of breath, swelling of ankles, and tiredness, changes in thinking<br>• Heart failure, heart attack which may cause shortness of breath, swelling of ankles, and tiredness<br>• Pain and swelling of thyroid<br>• Visual loss<br>• Difficulty swallowing<br>• A tear or hole in or between internal organs which may cause drainage and may require surgery<br>• Swelling of the gallbladder<br>• Liver damage which may cause yellowing of eyes and skin, swelling<br>• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat<br>• Flesh-eating bacteria syndrome<br>• Non-healing surgical site<br>• Change in the heart rhythm<br>• Kidney damage which may require dialysis<br>• Damage to the jawbone which may cause loss of teeth<br>• Damage to muscle which may cause muscle pain, dark red urine<br>• Cancer of bone marrow caused by chemotherapy<br>• Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions<br>• Stroke<br>• Brain damage which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)<br>• Sores on the skin<br>• Severe skin rash with blisters and peeling which can involve mouth and other parts of the body |

**Test and Procedure Risks**

In addition to the side effects for the drugs in this protocol there may be side effects associated with the tests and procedures that occur during this study. These include:

- Drawing blood: Risks associated include pain at the needle site, bruising, possible dizziness if you stand up quickly and possible inflammation of the vein or infection at the needle site. Care will be taken to avoid these complications.
- Scans, x-rays, and heart tests: There is a small risk of developing a reaction to the agents used during the test. Otherwise risk factors are similar to those associated with taking a blood sample which includes pain at the needle site, bruising, possible

dizziness if you stand up quickly and possible inflammation of the vein or infection at the needle site. Care will be taken to avoid these complications.

- An intravenous line will be used in some cases. There may be a risk of infection, blood clot or bleeding at the site of the line. There is also a risk of some of the drug leaking out, referred to as extravasation. If that occurs there may be some damage to skin tissue in a limited area. Patients are urged to alert the study physicians at the first sign of any skin changes, for example redness or tenderness around the infusion site or any discomfort near that area as well. If there is any evidence of toxicity from leaking, the infusion will be held until a central line can be placed for the infusion of drug. In addition, any toxic effects to the skin will be treated to the fullest extent possible. Development of air in the chest is a risk of a central line catheter. However, this complication is rare. Air in the chest outside the lung would require temporary placement of a chest tube by the surgeon.

For more information about risks and side effects, ask your study doctor.

## POTENTIAL BENEFITS OF PARTICIPATION

**Are there benefits to taking part in this study?**

Taking part in this study may or may not make your health better. The aim of this study is to see if the drug sunitinib malate will cause your tumor to shrink. We hope that you will get personal medical benefit from taking part in this study, but we cannot be certain. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the tumor. We do know that the information gained from this study will help doctors learn more about sunitinib as a treatment for cancer. This information could help future cancer patients.

## 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, with standard of care chemotherapy regimens
- 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 your disease gets worse 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. However, according to FDA guidelines, information collected on you up until that point may still be provided to the NCI or Pfizer, or designated representatives. If you withdraw from the study early, you may be asked if you will allow further medical information to be collected for study purposes. In that case, we would ask you to enroll on a separate protocol.

## 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 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. 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.

**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 (CTEP) or their agent(s)
- Qualified representatives from Pfizer, the pharmaceutical company who produces sunitinib

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, Arun Rajan, MD (rajana@mail.nih.gov or 240-760-6236). 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: _____.