THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

Consent Revision Date: 08/03/2016

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Pre-surgical Androgen Deprivation Therapy with or without Axitinib in Previously Untreated Prostate Cancer Patients with Known or Suspected LymphNode Metastasis
2011-0231

Subtitle: English ICF

Study Chair: Amado Zurita

1.

Participant's Name	Medical Record Number

You are being asked to take part in this clinical research study at The University of Texas MD Anderson Cancer Center ("MD Anderson"). This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you have high risk prostate cancer and are a candidate for surgery to remove your prostate.

2. PURPOSE OF STUDY

The goal of this clinical research study is learn if adding axitinib to hormonal therapy can help to control prostate cancer when given before surgery. The safety of this drug will also be studied.

3. DESCRIPTION OF STUDY

Study Drug

Axitinib is designed to block the formation of new blood vessels, which are involved in the growth and development of tumors.

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. You will have "screening tests" to help the doctor decide if you are eligible to take part in this study.

Within 60 days before you can be enrolled in this study, the following tests and procedures will be performed:

- You will have a chest x-ray and a computed tomography (CT) scan or a magnetic resonance imaging (MRI) scan of the chest, abdomen, and pelvis to check the status of the disease.
- You will have a bone scan to check the status of the disease.

Within 14 days before you can be enrolled in this study, the following tests and procedures will be performed:

- Your complete medical history will be recorded.
- You will be asked about any drugs or treatments you may be receiving (including over-the-counter drugs, herbal remedies, vitamins, and/or supplements).
- You will be asked about any disease-related symptoms you may be having.
- You will have a physical exam, including measurement of your height, weight, vital signs (temperature, blood pressure, breathing rate, and heart rate).
- You will have a digital rectal exam to check the status of the disease.
- You will be asked how well you are able to perform the normal activities of daily living (performance status).

Within 7 days before you can be enrolled in this study, the following tests and procedures will be performed:

- Blood (about 3-4 teaspoons) will be drawn for routine tests and to check your prostate-specific antigen (PSA) and testosterone levels. Your blood will also be tested for certain protein levels.
- Urine will be collected for routine tests.
- You will have an electrocardiogram (ECG) to check your heart function.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Study Groups
If you are found to be eligible to take part in this study, you will be randomly assigned (as in the roll of the dice) to 1 of 2 groups:

- If you are in **Group A**, you will receive axitinib and hormonal therapy.
- If you are in **Group B**, you will receive hormonal therapy alone.

You will have a 2 out of 3 chance of being placed in Group A. You have a 1 out of 3 chance of being placed in Group B.

Study Drug Administration
All participants will receive hormonal therapy. The hormonal drug you receive will be standard of care hormone therapy. The study doctor will decide what hormone therapy you will receive and will explain when and how you should take the hormone therapy and any risks.

You will have 8 weeks of hormone therapy before you are assigned to a study group. After you are assigned to a study group, you will receive up to 4 more months of hormone therapy.

If you are in Group A, you will also take 1 capsule of axitinib by mouth 2 times a day. You will be asked to take your blood pressure 2 times a week and record it in a diary before taking your axitinib dose. Note: If your blood pressure is above 150 systolic (the upper number) OR above 100 diastolic (the lower number) or if you develop any symptoms related to increased blood pressure please contact your study doctor immediately. You can take your blood pressure at home or elsewhere, such as at the drug store or doctors office. Doses should be taken about 12 hours apart and at about the same time each day, with food. If you miss a dose, you may take it up to 3 hours late before the next scheduled dose; otherwise do not make up the missed dose. Instead, skip the missed dose and take your next dose as scheduled. If you vomit any time after taking a dose do not make it up, but instead take your next dose as scheduled. You will be asked to keep a diary to help you keep track of when you take each dose of the study drug. Record any missed or vomited doses in the diary. Bring the diary with you to each visit.

Each cycle is 30 days. You should return all unused study drug and/or empty pill bottles at the end of each cycle.

Study Visits
At **every visit**, you will be asked about any side effects you have had and any drugs you may be taking.

About **8 weeks after you begin hormonal therapy**:

- Your medical history will be recorded.
- You will have a physical exam, including measurement of your weight and vital signs.
- Your performance status will be recorded.
- Blood (about 3-4 teaspoons) will be drawn for routine tests and to check your PSA. Your blood will also be tested for levels of certain proteins.
- You will have an ultrasound-guided biopsy of the prostate with 10-12 samples collected. You will be separately consented for this biopsy, which will describe the procedure and its risks in more detail.
- Blood (about 2 tablespoons) will be drawn for routine tests. Your blood will also be tested to check your thyroid function (Group A only).
- Urine will be collected for routine tests (Group A only).
- You will have an ECG (Group A only).

On **Day 15 of Cycle 1** (Group A only):

- Your vital signs and weight will be measured.
- Blood (about 3-4 teaspoons) will be drawn for routine tests.

On **Day 1 of Cycles 2 and 3** (Group A only):

- Your medical history will be recorded.
- You will have a physical exam, including measurement of your weight and vital signs.
- Your performance status will be recorded.
- Blood (about 3-4 teaspoons) will be drawn for routine tests to check your PSA and testosterone levels. Part of this blood will be used to check your thyroid function (Cycle 2 only).
- Urine will be collected for routine tests

About **2 months before surgery** (Group B only):

- Your medical history will be recorded.
- You will have a physical exam, including measurement of your weight and vital signs.

- Your performance status will be recorded.
- Blood (about 2 teaspoons) will be drawn to check your PSA and testosterone levels.

About **2 weeks before surgery** or **if you go off study early**:

- Your medical history will be recorded.
- You will have a physical exam, including measurement of your weight and vital signs.
- You will have a digital rectal exam.
- Your performance status will be recorded.
- Blood (about 3-4 teaspoons) will be drawn for routine tests and to check your PSA and testosterone levels. Your blood will also be tested for levels of certain proteins.
- You will have a CT scan or MRI scan of the chest, abdomen, and pelvis to check the status of the disease.
- You will have a bone scan to check the status of the disease.
- Blood (about 2 tablespoons) will be drawn for routine tests. Your blood will also be tested to check your thyroid function (Group A only).

Length of Study
You may receive the study drug(s) for about 6 months. You will be taken off study early if the disease gets worse, if you have intolerable side effects, or if your study doctor thinks it is in your best interest to stop.

Your participation on the study will be over once you have completed the follow-up visits after surgery.

Surgery
After 6 months of study treatment, you will have surgery to remove your prostate. You will be asked to sign a separate consent form for this surgery, and the risks will be discussed with you.

Long-Term Follow-Up

At **1 month after your surgery**:

- You will be asked about any drugs or treatments you may be receiving (including over-the-counter drugs, herbal remedies, vitamins, and/or supplements).
- You will be asked about any side effects you have had.
- You will have a physical exam, including measurement of your weight and vital signs.
- Your performance status will be recorded.
- Blood (about 2 teaspoons) will be drawn for PSA and testosterone levels.
- If you are in Group A, blood (about 2 tablespoons) will be drawn for routine tests and to check your thyroid function.

At **3 months after your surgery**:

- Your medical history will be recorded.
- You will be asked about any disease-related symptoms and/or side effects you may have had.
- You will have a physical exam, including measurement of your weight, height, and vital signs.
- Your performance status will be recorded.
- Blood (about 3-4 teaspoons) will be drawn for routine tests and to check your PSA and testosterone levels.

You will have follow-up visits every 3 months for the first year, every 4 months for the second year, every 6 months in the third to fifth year, and 1 time a year after that unless the disease worsens, you start taking hormone therapy, or you begin radiation treatments. At these visits, blood (about 3-4 teaspoons) will be drawn for routine tests and to check your PSA and testosterone levels.

This is an investigational study. Axitinib is not FDA approved or commercially available. Axitinib is currently being used for research purposes only.

If you are in Group A, axitinib will be provided at no cost to you during this study by Pfizer, Inc. You and/or your insurance provider will be responsible for the cost of hormone therapy.

Up to 72 patients will be enrolled in this study. All will be enrolled at MD Anderson.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects that the drugs are known to cause. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even lead to hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drug.

Axitinib Side Effects

Likely (occurring in more than 20% of patients)

• high blood pressure • fatigue • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood sugar (possible diabetes) • nausea • vomiting • diarrhea • weight loss • loss of appetite • abnormal digestive blood test (possible pancreas damage and/or inflammation of the pancreas)	• increased levels of hemoglobin in the red blood cells • weakness • abnormal liver tests (possible liver damage) • abnormal kidney test (possible kidney damage) • voice changes

Axitinib may likely cause low blood cell counts (red blood cells and/or white blood cells).

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Common (occurring in 3-20% of patients)

• blood clots in a vein (possible pain, swelling, and/or redness) • headache • dizziness • underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • low blood sugar	• skin rash • dry skin and/or itching • hair loss (partial or total) • dehydration • mouth blisters/sores • abnormal taste • abdominal pain • upset stomach • constipation	• hemorrhoids • blood in the urine • pain (muscle, joint, and/or arm/leg) • ringing in the ears • nosebleed • cough • difficulty breathing

Axitinib may commonly cause low platelet counts.

- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.

Rare but serious (occurring in fewer than 3% of patients)

• severe increase in blood pressure (possible stroke) • blood clots in an artery (possible organ damage such as stroke and/or heart attack) • heart failure • brain damage that may be reversible (possible headache, confusion, seizures, and/or vision loss)	• bleeding in the brain • stroke • fever • overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • bleeding or blood in the stool • hole in the intestines (possibly leaking contents into the abdomen)	• abnormal connections or passageways between organs or vessels • high red blood cell count (possible headache, dizziness, and/or stoke) • blood clot inside the eye (possible blindness) • blood clots in the lung (possible failure to breathe) • coughing up blood

Do not drink grapefruit juice, eat grapefruit, or take St. John's Wort while on this study.

You could also have an allergic reaction to the drug.

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life threatening. You should get medical help and contact the study doctor right away if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing, or swelling of the face, mouth, lips, gums, tongue or neck. Other allergic reactions may include rash, hives, or blisters.

You should tell the study doctor right away about all current drugs you are taking and any drugs you are considering taking while on this study.

If you are taking antacids and/or proton-pump inhibitors (such as cimetidine, famotidine, nizatidine, ranitidine, lansoprazole, rabeprazole, pantoprazole, esomeprazole, Maalox®, Milk of Magnesia®, or Amphojel®) you should not take them for at least 2 hours before or 2 hours after taking axitinib.

Hormone Therapy Side Effects

It is not known how often the following side effects may occur.

• increased risk for heart disease • depression	• increased risk for diabetes • hot flashes	• thin or brittle bones • increased body mass and higher levels of fats

• impaired thinking • nausea • diarrhea	• erection problems and reduced sex drive • breast enlargement	in the blood • reduced muscle mass

Hormonal therapy may cause low red blood cell counts. A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Additional Information
While on study, you must not take certain drugs. The drugs that you must not take while on study include the following:

• ketoconazole • miconazole • itraconazole • erythromycin • clarithromycin • telithromycin • verapamil • indinavir • saquinavir	• ritonavir • nelfinavir • lopinavir • atazanavir • amprenavir • osamprenavir • delavirdine • carbamazepine • dexamethasone	• felbamate • omeprazole • phenobarbital • amobarbital • phenytoin • primidone • rifabutin • rifampin • nevirapine

Bone marrow biopsies/aspirates and **ultrasound-guided prostate biopsies** may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the collection site. An allergic reaction to the anesthetic may occur. A scar may form at the collection site.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

4a. Because taking part in this study can result in risks to an unborn baby, you must use birth control during the study if you are sexually active.

Birth Control Specifications: You must use birth control during this study and must continue using birth control for 3 months after the study is over. The study doctor must approve the form of birth control.

If you or your partner becomes pregnant while you are on study or within 6 months after you have stopped taking the study drug, the sponsor would like to collect information about the pregnancy. The study sponsor's contact information will be made available so that, if you and your partner wish to, you can share information about the outcome of the pregnancy with the sponsor. If you and/or your partner choose not to share this information, it will not result in any penalty or loss of benefits to which you are otherwise entitled.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

5. POTENTIAL BENEFITS

Treatment with the study drug(s) may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

6. ALTERNATIVE PROCEDURES OR TREATMENTS

You may choose not to take part in this study. You may choose to have a prostatectomy with or without hormones without participating in this study. You may choose to have radiation therapy. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

OPTIONAL PROCEDURES FOR THE STUDY

If you agree, extra blood (about 2-3 tablespoons each time) will be drawn for biomarker testing. Biomarkers are chemical "markers" in the tissue that may be related to cancer, and they may help researchers predict who will respond to the study drugs.

- If you are in **Group A**, blood will be drawn at the screening visit, Day 15 of Cycle 1, Day 1 of Cycle 2, at Week 8, within 2 weeks before surgery, all of your Long-Term follow-up visits after surgery, and if the disease gets worse.
- If you are in **Group B**, blood will be drawn at the screening visit, at Week 8, 3 months before surgery, within 2 weeks before to surgery, all of your Long-Term follow-up visits after surgery, and if the disease gets worse.

If you agree, leftover tumor tissue will used for biomarker testing.

If you agree, leftover tissue from prior biopsies (including from outside institutions) will be collected and stored in a research tissue bank at MD Anderson for future research related to cancer.

If you agree, leftover blood, tissue, and/or bone marrow (left over from procedures you may have during this study) will be stored in a research tissue bank at MD Anderson for future research related to cancer.

Before your blood and tissue can be used for research, the people doing the research must get specific approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee made up of doctors, researchers, and members of the community. The IRB is responsible for protecting the participants involved in research studies and making sure all research is done in a safe and ethical manner. All research done at MD Anderson, including research involving your blood and tissue from this bank, must first be approved by the IRB.

Your samples will be given a code number. No identifying information will be directly linked to your samples. Only the researcher in charge of the bank will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed. Other researchers using your samples will not be able to link this data to you.

There are no benefits to you for taking part in the optional procedures. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

You do not have to agree to take part in the optional procedures in order to receive treatment on this study.

Optional Procedure Risks:
Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

MD Anderson and others can learn about cancer and other diseases from your **banked blood, tumor tissue, and bone marrow**. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with these samples, and these reports will not be put in your health records. If this information were released to you, your family, or third parties, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot ensure complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families. If the samples were used for this kind of research, the results will not be put in your health records. Research with your blood and tumor tissue may result in the development of beneficial treatments, devices, new drugs, or patentable procedures, from which you will not receive any financial benefits or compensation.

If you withdraw your consent to the storage of leftover blood, tumor tissue, and/or bone marrow in the tissue bank, then the leftover materials will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be removed from the tissue bank and destroyed.

However, if any of your de-identified blood, tumor tissue, and/or bone marrow was already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy it.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Do you agree to allow extra blood to be drawn for biomarker testing?

YES NO

Do you agree to allow leftover tumor tissue to be used for biomarker testing?

YES NO

Do you agree to allow for tissue from prior biopsies (including from outside institutions) to be collected?

YES NO

Do you agree to allow leftover blood, tissue, and bone marrow to be stored for in a research sample bank at MD Anderson for future research related to cancer?

YES NO

Additional Information

7. You may ask the study chair any questions you have about this study. You may contact the study chair, Dr. Amado Zurita, at 713-792-2830. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

9. This study or your participation in it may be changed or stopped at any time by the study chair, Pfizer, Inc., the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP - a regulatory agency that oversees research in humans), or the IRB of MD Anderson.

10. You will be informed of any new findings that might affect your willingness to continue taking part in the study.

11. MD Anderson may benefit from your participation and/or what is learned in this study.

12. This study is supported by: Pfizer, Inc..
13. The MD Anderson Conflict of Interest policy states that MD Anderson employees may not serve as the study chair or co-chair on a research study if they have received funds that are greater than the amount allowed by the policy or own stock in the sponsoring or supporting companies.

    The MD Anderson Conflict of Interest policy and the IRB require that you be told about significant financial relationships that the study staff and MD Anderson officials may have with the study sponsor(s).

    At this time, the following study staff have disclosed significant financial relationship(s) with the study sponsor(s):

    Dr. Amado Zurita (Study Chair) has received compensation from Pfizer as a Consultant. The financial interests are within the limits of the conflict of interest policy.

14. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s). If you have any questions about this, you may call the IRB at 713-792-2933.

STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Pfizer, Inc. for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research. You will receive no compensation for taking part in this study.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at MD Anderson will be collecting and using your protected health information. This information may include personal identifying information about you (such as your name, race, date of birth, gender, city, and zip code), your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section D below.

B. Signing this consent and authorization form is optional. However, if you refuse to provide your authorization to use and disclose your protected health information for this study, you will not be able to participate in this research project.

C. MD Anderson will take appropriate steps to keep your protected health information private when possible, and it will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point. Federal agencies (such as the FDA, OHRP, or National Cancer Institute [NCI]), Pfizer, Inc., and the IRB of MD Anderson might view or receive your record in order to collect data and/or meet legal, ethical, research, and safety-related obligations. In some situations, the FDA could be required to reveal the names of participants.

D. Your protected health information may be shared with the following parties:

- Pfizer, Inc. (and/or any future sponsors of the study)
- Federal agencies that require reporting of clinical study data (such as the FDA, NCI, and OHRP)
- The IRB of MD Anderson
- Officials of MD Anderson
- Study monitors who verify the accuracy of the information
- Individuals who put all the study information together in report form

E. Normally you have a right to access your medical record. However, in order to preserve the integrity of this research study, you will not be permitted to have access to certain portions of your medical record while the study is ongoing.

F. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study, and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related personal health information to preserve the scientific value of the study. Data collected about you up to the time you withdrew will be used and included in the data analysis. The parties listed in Section D above may use and disclose any study data that were collected before you canceled your authorization.

G. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF PARTICIPANT _____ DATE _____

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)
The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF LAR _____ DATE _____

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

RELATIONSHIP TO PARTICIPANT _____

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under Protocol **2011-0231**.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) _____ DATE _____

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT
I have discussed this clinical research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF STUDY CHAIR OR PERSON AUTHORIZED TO OBTAIN CONSENT _____ DATE _____

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE