THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

**Informed Consent**

# INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

## Phase I Trial of MK-3475 and Concurrent Chemo/Radiation for the Elimination of Small Cell Lung Cancer
## 2014-1003

**Subtitle**: 2014-1003

Study Chair: James Welsh

Participant's Name _____ Medical Record Number _____

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. You may choose not to take part in this study.

## 1. DESCRIPTION OF STUDY

The goal of this clinical research study is to find the highest tolerable dose of pembrolizumab (also called MK-3475) and radiation therapy (either with chemotherapy or alone) that can be given to patients with SCLC.

**This is an investigational study.** Radiation therapy is delivered using FDA-approved and commercially available methods for local control of metastatic and primary tumors. Pembrolizumab is FDA approved and commercially available for the treatment of unresectable or metastatic melanoma. It use in this study is investigational.

Pembrolizumab will be provided at no cost to you. You and/or your insurance company will be responsible for the costs of radiation, if you receive it.

Up to 80 patients will take part in this study. All will be enrolled at MD Anderson.

## 2. STUDY PROCEDURES

**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. If you have had some of these tests or procedures done recently, they may not need to be repeated.

- You will have a physical exam.
- You will have a computed tomography (CT) scan or positron emission tomography (PET) scan to check the status of the disease.
- Blood (about 4 teaspoons) will be drawn for routine tests.
- If you are able to become pregnant, you will have a blood (about ½ teaspoon) or urine pregnancy test. To take part in this study, you must not be pregnant.
- You will have a pulmonary function test (PFT) to check your lung function. The PFT involves breathing into a machine that measures how much air you breathe.

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 assigned to a part and study group based on when you join this study. Up to 3 groups of 3 participants each will be enrolled in Part A and up to 80 participants will be enrolled in Part B.

If you are enrolled in Part A or B, the dose of pembrolizumab you receive will depend on when you join this study. The first group of participants will receive the lowest dose level of pembrolizumab. Each new group will receive a higher dose of pembrolizumab than the group before it, if no intolerable side effects were seen. This will continue until the highest tolerable dose of pembrolizumab is found. All participants will receive pembrolizumab during radiation therapy. The radiation will be to the chest area. In addition to pembrolizumab, participants in Part A will also receive either cisplatin and etoposide or carboplatin and etoposide.

**Study Drug Administration**
You will receive pembrolizumab by vein over about 30 minutes on Day 1 of each 3-week cycle.

If you are in Group A, on Day 1 of Cycles 1-32, you will receive pembrolizumab by vein over 30 minutes. In addition, on Day 1 of Cycles 1-4, you will receive cisplatin by vein over about 2 hours and etoposide by vein over 4 hours on Days 1, 2, and 3. If you are unable to tolerate cisplatin, you will receive carboplatin by vein over 30 minutes and etoposide by vein over 4 hours on Days 1, 2, and 3.

**Study Visits**
When you are not receiving radiation, you will have these every 3 weeks.

- You will have a physical exam.
- Blood (about 1 tablespoon) may be drawn for routine tests.

**Follow Up**
Every 12 weeks after your last dose of pembrolizumab, you will have CT or PET scans to check the status of the disease. You will also have PFTs performed. If you are unable to make these visits, you will be contacted by phone to check your health.

**Length of Study**
You may continue taking the study drug for up to 32 doses. You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

**Other Information**
You are not allowed to receive any types of vaccinations while receiving the study drug.

## 3. POSSIBLE RISKS

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. 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 result in 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 treatment.

Carboplatin, cisplatin, etoposide, and pembrolizumab may each cause low blood cell counts (red blood cells, platelets, 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 platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet 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.

**Carboplatin Side Effects**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| ● 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) | ● vomiting<br>● low blood counts (red, white, platelets)<br>● pain | ● abnormal liver tests (possible liver damage)<br>● abnormal kidney test (possible kidney damage) |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| ● nerve damage (possible numbness, pain, and/or loss of motor function)<br>● hair loss (partial or total)<br>● abdominal pain | ● nausea<br>● constipation<br>● diarrhea<br>● abnormal taste<br>● weakness | ● abnormal liver tests (possible yellowing of the skin and/or eyes)<br>● allergic reaction<br>● infection |

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

| | | |
|---|---|---|
| ● high blood pressure<br>● low blood pressure (possible dizziness/fainting)<br>● heart failure<br>● stroke<br>● dehydration<br>● blood vessel blockage<br>● anemia due to destruction of red blood cells | ● multiple blood clots (possible organ dysfunction and/or failure)<br>● reduced blood supply to the arms and legs<br>● visual problems<br>● blindness<br>● hearing loss | ● difficulty breathing due to narrowing of the airways<br>● tissue death at the injection site caused by drug leakage<br>● life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) |

Carboplatin may rarely cause you to develop another type of cancer.

**<u>Cisplatin Side Effects</u>**

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| ● nausea<br>● vomiting | ● low blood counts (red, white, platelets)<br>● hearing loss, including | ● ringing in the ears<br>● kidney failure<br>● decreased kidney |

| | | |
|---|---|---|
| | high-frequency hearing loss | function |

**Exact frequency unknown but more than 10%**

| | | |
|---|---|---|
| ● tissue irritation | ● nerve damage (possible numbness, pain, and/or loss of motor function) | ● abnormal liver tests (possible liver damage) |

**Occasional (occurring in 1-10% of patients)**

| |
|---|
| ● none known at this time |

**Rare but serious (occurring in fewer than 1% of patients)**

| | | |
|---|---|---|
| ● low blood pressure (possible dizziness/fainting)<br>● irregular/slow/fast heartbeat<br>● heart failure<br>● heart attack<br>● reduced blood supply to the heart, arms, legs, and/or abdomen<br>● blood clots in a vein (possible pain, swelling, and/or redness)<br>● multiple blood clots (possible organ dysfunction and/or failure)<br>● abnormal blood clotting in small blood vessels (possible stroke and/or other organ damage)<br>● blood vessel inflammation of the brain<br>● blood vessel spasm (possible blockage of blood flow)<br>● brain injury that may be reversible (possible headache, confusion, seizures, and/or vision | ● decreased brain function (possible paralysis and/or coma)<br>● stroke<br>● seizure<br>● loss of feeling or movement due to spinal cord damage<br>● nerve damage (possible problems with the digestive system and/or heart<br>● high blood levels of fat (possible heart disease and/or stroke)<br>● 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)<br>● hormonal deficiency that affects the body's ability to control blood pressure and react to stress<br>● diarrhea<br>● dehydration | ● inflammation of the pancreas (possible abdominal pain)<br>● high blood levels of uric acid (possible painful joints and/or kidney failure)<br>● anemia due to destruction of red blood cells<br>● inflammation and/or swelling of an eye nerve (possible vision loss)<br>● blindness<br>● difficulty breathing due to narrowing of the airways<br>● life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)<br>● drug leakage from the injection site |

| | | |
|---|---|---|
| loss) | | |

**Frequency Unknown**

| | |
|---|---|
| ● abnormal taste | ● loss of motor function |

Cisplatin may cause you to develop another type of cancer.

The following side effects may be more severe in children: hearing damage, including high frequency hearing loss, ringing in the ears, and deafness.

**Etoposide Side Effects**

**Common (occurring in more than 20% of patients**

| | | |
|---|---|---|
| ● hair loss (partial or total) | ● nausea | ● vomiting<br>● low blood cell counts (red, white, platelets) |

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| ● loss of appetite<br>● diarrhea | ● mouth blisters/sores | ● abnormal liver tests (possible liver damage) |

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

| | | |
|---|---|---|
| ● low blood pressure (possible dizziness/fainting)<br>● heart attack<br>● decreased blood supply to the heart<br>● fever<br>● brain damage that may be reversible (possible headache, confusion, seizures, and/or vision loss)<br>● seizure<br>● severe sunburn-like rash at site of previous radiation (called radiation recall)<br>● very severe blistering skin disease (with ulcers of the skin and digestive | ● very severe blistering skin disease (loss of large portion of skin)<br>● enlarged bowel (possible abdominal pain)<br>● failure of the ovaries to produce hormones<br>● abnormal blood acid/base balance (possible organ damage)<br>● blood vessel spasm (possible blockage of blood flow)<br>● blood vessel inflammation (possible bleeding and/or bruising)<br>● nerve damage (possible | ● inflammation of an eye nerve<br>● lung inflammation and/or damage (possible difficulty breathing)<br>● blue skin<br>● drug leakage from the injection site (possible hardened tissue and/or tissue death)<br>● closing of the throat<br>● allergic reaction (possible interrupted breathing)<br>● life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) |

| | | |
|---|---|---|
| tract) | numbness, pain, and/or loss of motor function)<br>● blindness | |

Etoposide may cause you to develop another type of cancer (such as leukemia, a type of blood cancer).

High-dose etoposide also may cause the following side effects. It is not known how often these side effects may occur.

| | |
|---|---|
| ● symptoms of drunkenness (possible flushing and/or dizziness) | ● liver damage due to inflammation |

High-dose etoposide may cause you to develop another type of cancer.

## Radiation Therapy Side Effects

**It is not known how often the side effects of radiation therapy may occur.**

| | | |
|---|---|---|
| ● swelling<br>● swelling of the arms or torso<br>● skin changes (possible dryness, itching, peeling, and/or blistering) | ● hair loss at the treatment site<br>● trouble swallowing<br>● nausea<br>● vomiting<br>● diarrhea | ● urinary and/or bladder changes<br>● sexual changes<br>● inability to produce children<br>● joint problems<br>● lung inflammation (possible difficulty breathing)<br>● secondary cancers |

Radiation therapy may cause you to develop another type of cancer. Side effects may not occur for up to 6 months after radiation therapy is over. Side effects will vary depending on what part of the body is receiving radiation therapy.

## Pembrolizumab Side Effects

**Common (occurring in more than 20% of patients)**

| | | |
|---|---|---|
| ● fatigue<br>● fever<br>● skin rash and/or itching<br>● abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, | ● high blood sugar (possible diabetes)<br>● high blood levels of fat (possible heart disease and/or stroke)<br>● loss of appetite<br>● nausea<br>● constipation<br>● low blood cell count (white/red/platelets) | ● abnormal liver test (possible liver damage)<br>● pain<br>● abnormal kidney test (possible kidney damage)<br>● cough |

| | | |
|---|---|---|
| changes in mental status, and/or seizure) | | |

Pembrolizumab may cause low blood cell counts (red, white, and/or platelets):

- 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.
- 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.

**Occasional (occurring in 3-20% of patients)**

| | | |
|---|---|---|
| ● swelling (face/arm/leg)<br>● headache<br>● confusion<br>● underactive thyroid gland (possible weight gain, heart failure, and/or constipation)<br>● overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) | ● weight loss<br>● diarrhea<br>● vomiting<br>● abdominal pain<br>● blood in the urine<br>● abnormal liver tests (possible yellowing of the skin and/or eyes) | ● weakness<br>● nerve damage (possible numbness, pain, and/or loss of motor function)<br>● difficulty breathing (possibly due to lung inflammation)<br>● infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing) |

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

| | | |
|---|---|---|
| ● heart inflammation<br>● blood vessel inflammation (possible bleeding and/or bruising)<br>● seizure<br>● immune system damage to the nervous system (causing muscle weakness, numbness, and/or paralysis)<br>● spinal cord inflammation (possible pain, weakness, loss of feeling or movement, | ● hormonal deficiency that affects the body's ability to control blood pressure and react to stress<br>● pituitary gland inflammation (possible headaches)<br>● decreased production of adrenal hormones (possible weakness and/or low blood pressure)<br>● inflammation of the thyroid gland (possible | ● inflammation inside the eye (possible vision problems)<br>● kidney inflammation (possible kidney damage/failure)<br>● kidney failure<br>● build-up of fluid around the lungs<br>● immune response that causes the body to attack itself (possible organ damage)<br>● multi-organ disease causing lesions, most |

| | | |
|---|---|---|
| and/or paralysis)<br>● brain inflammation (possible paralysis and/or coma)<br>● shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids)<br>● large skin blisters<br>● very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) | tenderness in the neck)<br>● diabetes requiring insulin<br>● severe high blood sugar due to uncontrolled diabetes<br>● inflammation of the pancreas (possible abdominal pain)<br>● anemia due to destruction of red blood cells<br>● liver damage (hepatitis) | often in the lungs (sarcoidosis)<br>● immune response (causing muscle weakness)<br>● severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) |

If you have a solid tumor type and you have an organ transplant, pembrolizumab may increase your risk for the transplant to be rejected by your body.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue.

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

**Blood draws** 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**
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: While on study, you should use birth control pills, an intrauterine device (IUD), or implantable or injectable birth control (NorplantR or Depo-ProveraR started at least 3 months before joining the study). These must be used with a barrier method, such as a condom or diaphragm.

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

pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

## OPTIONAL PROCEDURES FOR THE STUDY

If you agree, you will have a core biopsy performed at screening and at Week 3 of Cycle 4 for immune system testing. To perform a core biopsy, you will be given local anesthesia and a sample of tissue is removed using a hollow core needle that has a cutting edge.

If you agree, tissue left over from the procedures performed while on this study will be collected and stored in a research bank at MD Anderson for use in future research related to immune system testing.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

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.

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.

**Optional Procedure Risks:**

Having biopsies performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

MD Anderson and others can learn about cancer and other diseases from your banked samples. 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 guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in

families.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they 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 destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

**CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES**

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

**Option #1:** Do you agree to allow leftover tissue (from a research sample bank, or from your diagnosis) to be obtained for immune system testing?

**YES NO**

**Option #2:** Do you agree to have a tumor tissue biopsy after completion of radiation therapy for immune system testing?

**YES NO**

## 4. POTENTIAL BENEFITS

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

## 5. OTHER PROCEDURES OR TREATMENT OPTIONS

You may choose to receive standard photon radiation therapy outside of this study. 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.

## 6. 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 Merck 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. 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.

## ADDITIONAL INFORMATION

7. You may ask the study chair (Dr. James Welsh, at 713-563-2300) any questions you have about this study. 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, Merck, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

10. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

12. This study is sponsored and/or supported by: Merck.

13. 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.

**Conflict of Interest**

Dr. James Welsh (Study Chair) has received compensation from Merck & Co. as a Scientific Advisor. The financial interests are within the limits of the conflict of interest policy.

Dr. Daniel Gomez (Study Co-Chair) has received compensation from Merck as a Consultant. The financial interests are within the limits of the conflict of interest policy.

**Authorization for Use and Disclosure of Protected Health Information (PHI):**

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Merck, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's

contracts require sponsors/supporters to protect this information and limit how they may use it.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, the data collected about you up to that point can be used and included in data analysis, but no further information about you will be collected.

E. 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 **2014-1003**.

**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 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 DATE
OR PERSON AUTHORIZED TO OBTAIN CONSENT

**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 |
|---|---|