PDOL Working Copy

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

Consent Revision Date: 04/09/2018

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Randomized, Placebo-Controlled, Phase 2 Study Of Induction Chemotherapy With Cisplatin/Carboplatin, And Docetaxel With Or Without Erlotinib In Patients With Head And Neck Squamous Cell Carcinomas Amenable For Surgical Resection
2013-0179

Study Chair: Xiuning Le

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 learn if adding erlotinib to a standard chemotherapy combination (docetaxel and either cisplatin or carboplatin) can help to control SCCHN. The safety of this drug combination will also be studied.

In this study, erlotinib will be compared to a placebo. A placebo is not a drug. It looks like the study drug but is not designed to treat any disease or illness. It is designed to be compared with a study drug to learn if the study drug has any real effect.

This is an investigational study. Erlotinib is approved by the FDA for treatment of non-small cell lung cancer. Its use in this study is experimental. Docetaxel, cisplatin, and carboplatin are all FDA approved and commercially available for the treatment of SCCHN.

Erlotinib/placebo will be provided at no cost to you while you are on study. You and/or your insurance company will be responsible for the costs of docetaxel and either cisplatin or carboplatin (whichever you receive).

Up to 100 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.

The following tests and procedures will be performed **within 30 days before** you can begin receiving the study drugs:

- You will have either a magnetic resonance imaging (MRI) or a computed tomography (CT) scan of all disease sites. If the study doctor thinks it is needed, you will have additional imaging scans.
- Blood (about 2 teaspoons) will be drawn for biomarker testing.
- You will have a tumor tissue biopsy (possibly 2 at the same time if needed) for biomarker testing. Biomarkers are in the tissue/blood and may be related to your reaction to the study drug(s). These biomarker tests may also include genetic studies. To collect a tissue biopsy, the affected area is numbed with anesthetic and a small cut is made to remove a small amount of tissue.

Within 14 days before you can begin receiving the study drugs:

- You will have a physical exam.
- You will be asked about your current smoking status and tobacco use.
- Blood (about 2-3 teaspoons) will be collected for routine tests. If you can become pregnant, this routine blood collection will include a pregnancy test. To take part in this study, the pregnancy test must be negative. If you want, you may have a urine pregnancy test instead.
- You will be given a questionnaire about how you feel about different aspects of your daily life. It should take you about 15 minutes to complete the questionnaire.
- If the doctor thinks it is needed, you will have additional imaging scans.

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 flip of a coin) to 1 of 2 study groups (also known as an Arm):

- If you are in **Arm A**, you will receive standard chemotherapy in combination with erlotinib.
- If you are in **Arm B**, you will receive standard chemotherapy in combination with a placebo.

If you are 1 of the first 30 patients to be enrolled on the study, you will have an equal chance of being assigned to either group. If you are one of the next 20 patients to be enrolled on the study, you will have a higher chance of being assigned to the group that appears to be performing better. Up to 50 more participants will then be assigned to a study group based on the results seen in the first 50 participants.

Neither you nor the study doctor will know if you are receiving erlotinib or placebo. However, if needed for your safety, the study doctor will be able to find out what you are receiving.

Study Drug Administration

You will receive docetaxel and either cisplatin or carboplatin by vein on Day 1 of up to 3 study cycles, over about 1-2 hours. The study doctor will tell you whether you are receiving cisplatin or carboplatin. Each study cycle will be 3 weeks.

You will also take tablets of either erlotinib or placebo every day until (and including) the day before your scheduled surgery. You should take the tablets with about 1 cup (8 ounces) of water. You should take the tablet on an empty stomach, at least 1 hour before or 2 hours after a meal. You should take the tablet at around the same time each day, preferably in the morning. Your eating habits around the time you take the tablet should stay the same while you are on study. If you vomit, and you can actually see the tablet, you may take another tablet. If not, you should not take another tablet until your next scheduled dose.

You will continue to take erlotinib or placebo daily until the day prior to surgery (including the day prior to surgery).

You will be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

Study Visits

On **Day 1 of each Cycle**, you will receive the study drugs, as described above.

Within 7 days before Cycles 2 and 3:

- You will have a physical exam.
- You will be asked about your current smoking status and tobacco use.
- Blood (about 2-3 teaspoons) will be drawn for routine tests.

At least 14 days after the last dose of chemotherapy:

- You will have a physical exam.
- You will be asked about your current smoking status and tobacco use.
- Blood (about 2-3 teaspoons) will be drawn for routine tests.
- You will have an MRI or CT scan of the head and neck. If the study doctor thinks it is needed, additional imaging scans may be performed.
- You will complete a questionnaire about how you feel about different aspects of your daily life. It should take you about 15 minutes to complete the questionnaire.
- Blood (about 1-2 teaspoons) will be drawn for biomarker and pharmacokinetic (PK) testing. PK testing measures the amount of study drug in the body at different time points.

At any point while you are on study, if you can become pregnant and your doctor thinks it is needed, you will have a blood (about 1 teaspoon) or urine pregnancy test.

Surgery

After you stop taking the study drug/placebo, you will have the surgery you were already scheduled to receive. You will sign a separate consent form that describes the surgery and its risks. As part of this study, tumor tissue will be collected during the surgery and checked for the status of the disease as well as any spread of the disease.

Length of Study

You may receive the standard chemotherapy combination for up to 3 cycles. You may take the study drug/placebo up until the day before surgery. If you have side effects from the chemotherapy, it is possible that you may stop taking the chemotherapy combination and continue to receive the study drug/placebo up until surgery. 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.

Your active participation on the study will be over after the end-of-treatment visit.

End of Treatment Visit

About 8 weeks after surgery, the following tests and procedures will be performed:

- You will have a physical exam.
- Blood (about 1-2 teaspoons) will be drawn for biomarker and PK testing.
- You will complete the questionnaire about your daily life.
- If you can become pregnant and your doctor thinks it is needed, you will have a blood (about 1 teaspoon) or urine pregnancy test.

Long Term Follow Up

After the end of treatment visit, you will be called at least 1 time each year to check on how you are doing. You (or your family members or designees) may be contacted by telephone, in writing, by e-mail, or during clinic visits. It is important to keep your contact information up to date with the study staff. This information may also be collected by checking your medical record.

Additional Information

- You should not drink grapefruit juice or eat grapefruit while you are taking part in this study.
- Avoid taking medications that will lower your level of stomach acid while taking erlotinib [for example, Zantac (ranitidine), Pepcid (famotidine), Tagamet (cimetidine), Protonix (pantoprazole), Nexium (esomeprazole), Prilosec (omeprazole), Prevacid (pantoprazole), or Aciphex (rabeprazole)].
- Short-acting antacids (such as Tums, Maalox, Mylanta, and Rolaids) may be taken while on erlotinib, as long as they are not taken 2 hours before or after your dose of erlotinib.
- Tell your doctor if you have any side effects. You may be given drugs to help lower the risk of side effects, or your study drug level may be changed or stopped for a short time.

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 drug/procedures.

Erlotinib, docetaxel, cisplatin, and carboplatin each may cause low blood cell counts (red blood cells, platelets, and 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.

Erlotinib Side Effects

Common (occurring in more than 20% of patients)

• fatigue • skin rash • dry skin • diarrhea	• loss of appetite • nausea • vomiting	• weakness • cough • difficulty breathing

Occasional (occurring in 3-20% of patients)

• chest pain • swelling (arm/leg)	• hand-foot syndrome (palms of hands/soles of feet having pain,	• nosebleed • abnormal liver tests (possible liver

• headache • anxiety • dizziness • difficulty sleeping • nervous system damage • fever • itching • hair loss (partial or total) • skin redness/sores/blisters/ rash (possibly acne-like) • nail changes • shedding and scaling of the skin (possible fatal loss of bodily fluids)	swelling, and blistering) • hair growth • mouth blisters/sores (possible difficulty swallowing) • abdominal pain • constipation • weight loss • upset stomach • dry mouth • abnormal sensation (such as pins and needles) • low blood cell counts (red, white, and/or platelets)	damage and/or yellowing of the skin/eyes) • muscle spasms • pain (muscle/joint/bone/back) • eye disorders (such as painful red eyes and/or dry eyes) • voice changes • blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • difficulty breathing due to lung inflammation and/or damage

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

• skin disorders (possible blistering and/or peeling of the skin) • severe skin damage (possibly resulting in inflammation of the bowel and/or loss of a large portion of skin) • low blood levels of potassium (possible weakness and/or muscle cramps) • stomach and/or small intestine ulcer (possible bleeding)	• vomiting of blood • hole in the intestines (possibly leaking contents into the abdomen) • tarry/coffee ground-like/bright red blood in the stool • liver damage • liver and/or kidney failure (possibly resulting in death)	• inflammation of/inside the eye (possible vision problems) • sores and/or a small hole in the front part of the eye • hearing loss • painful torn eardrum • abnormal kidney test (possible kidney damage) • damage of the small airways with difficulty breathing

Erlotinib may interact with certain statin drugs (drugs usually given to lower your cholesterol) and cause rare episodes of rhabdomyolysis (breakdown of muscle tissue, which can cause kidney failure).

Docetaxel Side Effects

Common (occurring in more than 20% of patients)

• swelling • nerve damage (loss of motor or sensory function) • fever • hair loss (partial or total) • skin rash/itching • nail changes	• mouth blisters/sores (possible difficulty swallowing) • diarrhea • nausea • vomiting • low blood cell counts (red, white)	• weakness • muscle pain • lung problems (possible shortness of breath) • infection • allergic reaction

Occasional (occurring in 3-20% of patients)

• severe heart problems • low blood pressure (possible dizziness/fainting) • abnormal taste • low platelet counts	• abnormal liver or bone tests (possible liver damage, yellowing of the skin and/or eyes) • joint pain	• infusion-site reactions (such as darkening of the skin, inflammation, redness, dryness, drug leakage from the injection site, and/or vein inflammation/swelling)

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

• fast/irregular heartbeat • build-up of fluid in the tissue around the heart (possible heart failure) • chest pain/tightness (possibly due to heart trouble) • heart attack/failure • high blood pressure • blood clots in a vein (possible pain, swelling,	• severe sunburn-like rash at site of previous radiation (called radiation recall) • low blood levels of sodium (possible headache, confusion, seizures, and/or coma) • dehydration • digestive system bleeding • intestinal blockage	• eye disorder (possible vision loss) • hearing loss • kidney failure • difficulty breathing (possibly due to narrowing of the airways) • fluid in or around the lung (possible difficulty breathing)

and/or redness) • loss of consciousness • fainting • seizure • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • severe hardened skin (possible difficult movement)	• hole in the intestines (possibly leaking contents into the abdomen) • decreased blood flow to part of the bowel (possibly causing death of tissue) • small intestine ulcer • fluid in the abdomen • DIC (breakdown of the blood clotting system) (possible severe bleeding, organ dysfunction, and/or organ failure) • liver damage • blockage of the tear ducts (possible teary eyes)	• blockage in the lung (possible pain and/or shortness of breath) • lung damage/inflammation (possible difficulty breathing) • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • lupus (an immune system disease) • multiorgan failure • swelling of the retina (possible vision loss)

Docetaxel may rarely cause you to develop another type of cancer (such as acute myeloid leukemia [a type of blood cancer]).

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

• fatigue • skin peeling	• weight gain	• painful or abnormal skin sensations (such as pins and needles)

Docetaxel contains alcohol and may cause you to feel drunk. You should avoid driving, operating heavy machinery, or performing other activities that are dangerous for 1-2 hours after your dose of docetaxel. Certain drugs, such as pain relievers and sleep aids, may make this side effect worse.

There may be a higher chance of death from docetaxel in people with certain medical histories. Your doctor can discuss this with you.

<u>Cisplatin Side Effects</u>

Common (occurring in more than 20% of patients)

• nausea • vomiting	• low blood counts (red, white, platelets) • ringing in the ears	• kidney failure • decreased kidney function

Exact frequency unknown but more than 10%

• nerve damage (possible numbness, pain, and/or loss of motor function)	• abnormal liver tests (possible liver damage)

Occasional (occurring in 1-10% of patients)

• tissue irritation

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

• low blood pressure (possible dizziness/fainting) • irregular/slow/fast heartbeat • heart failure/attack • reduced blood supply to the heart, arms, and/or legs • blood clots in a vein (possible pain, swelling, and/or redness) • multiple blood clots (possible organ dysfunction and/or failure) • blood vessel inflammation of the brain • brain injury that may be reversible (possible headache, confusion,	• stroke • seizure • loss of feeling or movement due to spinal cord damage • nerve damage (possible problems with the digestive system and/or heart) • high blood levels of fat (possible heart disease and/or stroke) • 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)	• inflammation of the pancreas (possible abdominal pain) • high blood levels of uric acid (possible painful joints and/or kidney failure) • anemia due to destruction of red blood cells • destruction of red blood cells (possible kidney damage and/or failure) • inflammation and/or swelling of an eye nerve (possible vision loss) • blindness • vision changes • difficulty breathing due to narrowing of

seizures, and/or vision loss) • decreased brain function (possible paralysis and/or coma)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • diarrhea • dehydration	the airways • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • drug leakage from the injection site

Frequency Unknown

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

Cisplatin may cause you to develop another type of cancer.

<u>Carboplatin Side Effects</u>

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 • low blood counts (red/ white/platelets) • pain	• abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • abnormal kidney test (possible kidney damage)

Occasional (occurring in 3-20% of patients)

• nerve damage (possible numbness, pain, and/or loss of motor function) • hair loss (partial or total)	• abdominal pain • nausea • constipation	• diarrhea • weakness • allergic reaction • infection

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

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

Carboplatin may rarely cause the cancer to spread.

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.

<u>Other Risks</u>

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.

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests will not be put in your health records. If this information were released, 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.

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

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

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: If you can become pregnant or father a child, you must use effective birth control measures while on study and for at least 30 days after you stop taking the study drugs. Effective birth control methods include barrier methods (such as a condom or diaphragm) in combination with spermicide. Talk to the study doctor about effective methods of birth control.

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, blood and tissue left over from the procedures performed on this study will be collected and stored in a research bank at MD Anderson for use in future research related to cancer.

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

Optional Procedure Risks:
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. Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. If this happens, there are no plans to compensate you. 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 medical record. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty getting insurance coverage and/or a job.

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 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 samples left over from procedures performed on this study to be stored in a research bank at MD Anderson for use in future research related to cancer?

YES NO

4. POTENTIAL BENEFITS

The study drugs 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 chemotherapy, radiation, surgery, and/or combined modality approaches. 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, Astellas Pharmaceuticals, OSI Pharmaceuticals, or Kadoorie Foundation 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. Xiuning Le, at 713-792-6363) 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, Astellas Pharmaceuticals, OSI Pharmaceuticals, Kadoorie Foundation, 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: Astellas Pharmaceuticals, OSI Pharmaceuticals, and Kadoorie Foundation.
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.

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
- Astellas Pharmaceuticals, OSI Pharmaceuticals, and Kadoorie Foundation, who are sponsors or supporters 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 **2013-0179**.

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 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