THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

**Informed Consent**

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

## Local Consolidative Therapy (LCT) and Durvalumab (MEDI4736) for Oligoprogressive and Polyprogressive Stage III NSCLC after Chemoradiation and Anti-PD-L1 Therapy (ENDURE) 2020-1031

Study Chair: Joe Chang

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

## STUDY SUMMARY

The goal of this clinical research study is to learn if using a combination of radiation therapy and/or surgery with durvalumab can help to control non-small cell lung cancer (NSCLC). Researchers also want to learn if this can help to extend the effects of durvalumab after the cancer has metastasized (spread).

Some participants will also receive standard chemotherapy based on the type of disease they have.

**This is an investigational study.** Radiation therapy is delivered using FDA approved and commercially available methods. Durvalumab is FDA approved and commercially available for the treatment of advanced NSCLC. It is considered investigational to use a combination of surgery/radiation therapy and durvalumab in patients whose disease has gotten worse after receiving immunotherapy (such as durvalumab). If you receive chemotherapy, the type you receive will be FDA approved and commercially available for the type of disease that you have.

The study doctor can explain how radiation therapy and the study drug are designed to work.

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.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects, some of which may be severe or fatal. You can read a list of potential side effects below in the Possible Risks section of this consent.

If you receive it, you will receive radiation therapy for up to 3 weeks. You may continue to receive the study drug for as long as the study doctor thinks it is in your best interest.

You and/or your insurance company will be responsible for the costs of radiation therapy and/or surgery. If you receive standard chemotherapy, you and/or your insurance provider will also be responsible for its costs. Durvalumab will be provided at no cost to you.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard radiation therapy or other therapies outside of this study. The study doctor will discuss these therapies with you, including their risks and benefits. 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.

## 1. STUDY DETAILS

**Screening Tests**

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

- You will have a physical exam.
- You will have triplicate EKG (3 EKGs in a row) to check your heart function.
- Blood (about 4-6 teaspoons) will be drawn for routine tests and research tests. On this study, “research tests” will refer to biomarker testing and/or tests of the immune system. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.
- Urine will be collected for routine tests.
- You will have a CT scan, PET/CT scan, and/or an MRI to check the status of the disease. If the doctor thinks it is needed, you may have an ultrasound or x-ray.
- You will have a tumor biopsy to check for certain mutations (changes) and for biomarker testing. The study doctor can explain more about this procedure and its risks.
- You will collect a stool sample for microbiome testing (a type of testing that checks for certain bacteria and microorganisms).
- You will complete a series of questionnaires about how you are doing and any side effects you may be having. These will take about 30 minutes to complete.
- If you can become pregnant, blood (about 2 teaspoons) or urine will be collected for a pregnancy test within 7 days of your first dose of the study drug. To take part

in this study, you must not be pregnant.

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

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 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 Group A if you have a few tumor sites (up to 3) or Group B if you have many tumor sites (more than 3).

- If you are in **Group A,** you will receive surgery/radiation and durvalumab.
- If you are in **Group B**, you will receive surgery/radiation, durvalumab, and standard of care chemotherapy. The study doctor will discuss your standard chemotherapy. You will be given separate consent forms for these treatments that describe their risks.

If the study doctor thinks surgery is in your best interest, you will receive a separate consent form that describes the procedure and its risks. It is possible that you will receive surgery, radiation therapy, or both.

Depending on the type of radiation that is chosen for you, you may receive radiation anywhere between 3 days to 3 weeks. The study doctor will discuss what type of radiation you will have and how often you will receive it.

Within 7 days before you begin radiation therapy, you will have radiation simulation to plan radiation treatment. During radiation simulation, you will go through the motions of receiving radiation (though you will not receive radiation) to help you understand the radiation process. This will also help the doctor know where to "aim" the radiation when you receive radiation. This may take up to 1 hour.

If there is additional tumor(s) that may benefit from being removed, surgery may be recommended. The study doctors will discuss your standard surgery with you. You will be given separate consent forms for surgery that describe their risks.

Up to 51 participants will take part in this study. All will take part at MD Anderson.

**Study Drug Administration**

After radiation and/or surgery, you will receive durvalumab. If you are in Group B, you will receive durvalumab in combination with standard chemotherapy. These therapies will be given every 3-4 weeks. The length of each of these cycles will depend on whether or not you are also receiving chemotherapy.

Durvalumab will be given by vein over about 1 hour. The chemotherapy administration

will be described in your other consent forms and by the study staff.

If you are still receiving durvalumab or chemotherapy when the study ends, you may continue to receive it if the study doctor thinks it is in your best interest. You will no longer be able to receive the study drug(s) if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

**Study Visits**

You will have study visits on **Day 1 of each 3-4 week study cycle**. At each visit:

- You will have a physical exam.
- Blood (about 4-6 teaspoons) will be drawn for routine tests. At Cycles 1, 2, 4, and every 3 cycles after that (Cycles 7, 11, 14, and so on), this sample will also be used for research tests. If you can become pregnant, part of this sample or urine will be collected for a pregnancy test.
- Additionally, certain tests will only be done at certain visits:
    - You will collect a stool sample at Cycle 1.
    - You will have a biopsy after Cycle 2 to compare to the sample taken at screening.
    - You will have the same imaging scans you had at screening to check the status of the disease at Cycles 2, 4, and every 3 cycles after that.
    - You will repeat the symptom questionnaire at Cycle 4 and every 3 cycles after that.

**End of Treatment Visit**

About **30 days** after the last dose of durvalumab:

- You will have a physical exam.
- Blood (about 4-6 teaspoons) will be drawn for routine tests. If the disease got worse, part of this sample will be used for research tests. If you can become pregnant, part of this sample or urine will be collected for a pregnancy test.
- You will complete the symptom questionnaires.
- You will collect a stool sample.

**Follow Up**

About 60 and 90 days after the last dose, blood (about 4-6 teaspoons) will be drawn for routine tests. At the 90-day visit, you will also complete the symptom questionnaires.

Every 2 months, you will be called and asked about how you are doing. Each call should take about 5-10 minutes.

Every 12 weeks, you will repeat the symptom questionnaires and have the same imaging scans you had at screening to check the status of the disease.

One (1) year after the last dose, and then every 6 months after that, blood (about 4-6

teaspoons) will be drawn for routine tests.

**Other Instructions**
You should not receive a live vaccine while receiving durvalumab and for up to 30 days after the last dose of durvalumab.

**Additional Study Participation**
As part of this study, you will also be enrolled on LAB09-0983 and will have all or some of the following tests/procedures:

- Blood (about 2-4 tablespoons) will be drawn to measure the levels of circulating tumor cells (CTCs) or circulating tumor DNA (CTDNA) found in the blood. DNA is the genetic material of cells.
- You may have a mouth swab or rinse to study the bacteria make up in the mouth. Studying bacteria can help researchers understand the interaction of bacteria in the body with the immune system.
- You may complete questionnaires about your medical, surgical, family, and social history, any drugs you may be taking, and any other relevant information that researchers may need to know about your overall health.

You will sign a separate LAB09-0983 consent explaining the study and its risks. **You cannot take part in this study if you do not take part in LAB09-0983.**

## 2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. 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.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

**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)<br>• headache | • hair loss at the treatment site<br>• mouth problems<br>• trouble swallowing<br>• nausea<br>• vomiting<br>• diarrhea<br>• brain tissue damage (necrosis) | • urinary and/or bladder changes<br>• sexual changes<br>• inability to produce children<br>• joint problems<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.

## Durvalumab Side Effects

The study drug durvalumab works by boosting the immune system. Side effects as a result of stimulating the immune system have been reported in patients being given durvalumab. These immune system side effects are included in the risks outlined below. Durvalumab 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.

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

| | | |
|---|---|---|
| • fatigue<br>• skin rash<br>• high blood sugar (possible diabetes) | • abnormal salts, minerals, and/or acids in the blood (which may cause weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)<br>• constipation<br>• abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) | • pain (such as muscle/joint)<br>• lung inflammation (possible difficulty breathing)<br>• cough<br>• infections (upper respiratory infections, pneumonia, influenza, dental and oral soft tissue infections, oral thrush) |

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

| | | |
|---|---|---|
| • swelling (arms/legs)<br>• fever | • overactive thyroid gland (possible weight | • low blood cell count (red, white) |

| | | |
|---|---|---|
| • voice disorder/hoarse voice<br>• night sweats<br>• itching<br>• underactive thyroid gland (possible weight gain, heart failure, and/or constipation) | loss, heart rate changes, and/or sweating)<br>• loss of appetite<br>• inflammation of the intestines<br>• diarrhea<br>• abdominal pain<br>• nausea/vomiting<br>• dehydration<br>• difficult and/or painful urination | • liver damage/inflammation (hepatitis)<br>• kidney inflammation or injury (possible kidney failure or decreased kidney function)<br>• difficulty breathing |

Durvalumab may cause low blood cell counts (red blood cells 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 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.

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

| | | |
|---|---|---|
| • inflammation of the heart (or the membrane surrounding the heart)<br>• inflammation of the brain or membranes around the spinal cord and brain (possible headache and/or coma)<br>• immune system damage to the nervous system (causing weakness, numbness and/or paralysis)<br>• inflammation of blood vessels<br>• hardening/tightening of the skin and connective tissue<br>• inflammation of skin (dermatitis) or patches of skin color loss<br>• skin blisters | • pituitary gland failure/inflammation (possible headaches, thirst, and/or irregular periods in women)<br>• type 1 diabetes which requires insulin<br>• high blood sugar<br>• hole in the intestines (possibly leaking contents into the abdomen)<br>• inflammation of the pancreas (possible abdominal pain)<br>• anemia due to destruction of red blood cells<br>• low platelet count<br>• immune response (causing joint, tissue, and/or organ damage) | • inflammation and weakness of multiple muscles<br>• inflammation inside/around the eye (possible vision problems)<br>• immune reaction (possible loss of drug function)<br>• lung damage<br>• infusion reaction (possible chills, fever, difficulty breathing, and/or change in blood pressure)<br>• multi-organ disease causing lesions, most often in the lungs (sarcoidosis)<br>• allergic reaction or over-activated immune system causing swelling |

| | | |
|---|---|---|
| • decreased production of adrenal hormones (possible weakness and/or low blood pressure) | | of face, lips, or throat, fever, or shortness of breath |

Durvalumab may cause low blood cell counts (platelets). 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.

Patients with head and neck cancer may have an increased risk of bleeding. Tell the study doctor right away if you experience any bleeding and about any drugs you are taking that may increase your risk of bleeding (such as aspirin, blood thinners, or NSAIDs).

**Using the study drug together with chemotherapy** 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.

## Other 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.

**EKGs** may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

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. Rarely (in fewer than 3% of patients), major bleeding may occur. Occasionally (in 8-12% of patients), you may have a collapsed lung and need to have a chest tube surgically placed. In 15-20% of patients, a collapsed lung that does not require placement of a chest tube may occur.

**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.

Collecting a **stool sample** may make you feel uncomfortable.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the

MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

**PET and CT scans** send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel "closed in" while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

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: Talk with the study doctor about acceptable methods of birth control to use while on study and for how long you should use them.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy. A male condom plus spermicide should be used from screening to 90 days after the last dose of durvalumab monotherapy Do not father a child or donate sperm during the study and for 180 days after the last dose of chemotherapy or 90 days after the last dose of durvalumab, whichever is the longer time period.

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. You must use effective birth control (barrier, intrauterine, and/or hormonal methods) from screening to 90 days after the last dose of durvalumab monotherapy.

Getting pregnant may result in your removal from this study.

## OPTIONAL PROCEDURES FOR THE STUDY

**Optional Procedure #1:** If you agree, you will have an additional tumor biopsy if the

disease appears to get worse while on study. To perform a biopsy, you will be given local or general anesthesia and a sample of tissue will be removed using a hollow core needle that has a cutting edge.

**Optional Procedure #2:** If you agree, blood (about 4-6 teaspoons) will be drawn if the disease appears to get worse while on study. This will be used for biomarker testing, including genetic biomarkers.

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

## CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

**Optional Procedure #1:** Do you agree to have an additional tumor biopsy if the disease appears to get worse while on study?

**YES** **NO**

**Optional Procedure #2:** Do you agree to have blood drawn if the disease appears to get worse while on study?

**YES** **NO**

## 3. 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 AstraZeneca for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 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.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

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

**4.** You may ask the study chair (Dr. Joe Chang, 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 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

**5.** 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 who can help you safely stop study treatment. It may be dangerous to suddenly stop study treatment. The study doctor will also decide if you need to have any visits or tests to check on your health. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database. The study staff may ask if they can continue collecting the results of routine care from your medical record. If you agree, this data will be handled the same as research data.

**6.** This study or your participation in it may be changed or stopped without your consent at any time by the study chair, AstraZeneca, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. Possible reasons your participation in this study may be stopped include if the disease gets worse, if intolerable side effects occur, if you are unable to follow study directions, or if the study is stopped.

**7.** 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.

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

**9.** This study is supported by: AstraZeneca.

**10.** In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

## Future Research

### Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and AstraZeneca and/or shared with other researchers and/or institutions for use in future research.

### Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. AstraZeneca will not receive leftover samples.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

### Genetic Research

Research samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

**Conflict of Interest**

Outside relationships are disclosed to and approved by the Conflict of Interest Committee, which reviews these relationships for compliance with institutional policy. This review helps the IRB to assure that financial relationships do not have an impact on the conduct of this study. The following members of the study staff have disclosed compensation from the funding source(s) of this study:

- Joe Chang (Principal Investigator)
- Marcelo Vailati Negrao (Co-Investigator)
- Stephen Chun (Co-Investigator)

**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
- AstraZeneca, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Any future sponsors and/or licensees of the study technology
- 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.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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 andsign.

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 at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, 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. Youcan 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.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

**WITNESS TO CONSENT**

I was present during the explanation of the research to be performed under this protocol.

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

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

**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.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT