THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Phase II Study of Neoadjuvant Gemcitabine, Nab-paclitaxel, Durvalumab (MEDI4736) (anti-PD-L1), and Oleclumab (anti-CD73) in the Treatment of Resectable/Borderline Resectable Primary Pancreatic Adenocarcinoma

2020-0898

Study Chair: Brandon Smaglo, MD

_____ _____
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 the combination of gemcitabine, nab-paclitaxel, durvalumab, and oleclumab can help to control pancreatic cancer. The safety of the drug combination will also be studied.

This is an investigational study. Gemcitabine and nab-paclitaxel are FDA approved and commercially available for the treatment of pancreatic cancer. Durvalumab and oleclumab are considered investigational and are not FDA approved. They are currently being used for research purposes only. The study doctor can explain how the drugs are designed to work.

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

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 full list of potential side effects below in the Possible Risks section of this consent.

You may receive study treatment for up to 6 months.

The investigational drugs, durvalumab and oleclumab, will be provided to you at no cost on this study. You and/or your insurance provider will be responsible for the cost of gemcitabine and nab-paclitaxel.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive other treatments, including chemotherapy. You should discuss these with the study doctor. The study doctor will discuss the possible risks and benefits of these treatments. 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 be done within 28 days before your first dose of study drug(s) to help the doctor decide if you are eligible:

- You will have a physical exam.
- You will have an EKG to check your heart function.
- Blood (about 4 teaspoons) will be drawn for routine tests, to check for viruses like hepatitis and HIV (the AIDS virus), to check for genetic mutations (changes), and for tumor marker and biomarker testing, which may include genetic biomarkers. Tumor markers may be related to the status of the disease. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. If you can become pregnant, part of this draw will be used for pregnancy testing. To take part in this study, you must not be pregnant.
- Urine will be collected for routine tests.
- You will have a CT scan or MRI to check the status of the disease.
- You will have a fresh tumor biopsy collected for future research.

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.

Up to 30 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each cycle is 28 days.

Before Surgery (2-6 cycles)

On **Days 1 and 15 of each cycle**, you will receive oleclumab, gemcitabine, and nab-paclitaxel by vein. The oleclumab infusion should take about 1 hour. The nab-paclitaxel infusion should take about 30-40 minutes. Right after your nab-paclitaxel infusion, you will receive the gemcitabine infusion over about 30 minutes.

On **Day 1 of each cycle**, you will also receive durvalumab by vein over about 1 hour.

These drugs will be given using a central venous catheter (CVC). A CVC is a sterile flexible tube that will be placed into a large vein while you are under local anesthesia. Your doctor will explain this procedure to you in more detail, and you will be required to sign a separate consent form.

About 3-9 weeks after the last dose of study drugs, you will undergo surgery to remove the tumor.

Post-Surgery

After surgery, the study doctor will decide how to continue to treat the cancer and discuss these options with you. You may be given treatment with (1) durvalumab and oleclumab, (2) durvalumab, oleclumab, gemcitabine, and nab-paclitaxel, (3) other chemotherapy only, or (4) no treatment, or observation only.

You will receive up to a total of 12 months of study treatment given before and after surgery.

Your participation in the study will last until you withdraw or the study ends. Your doctor may remove you from the study if the disease gets worse, intolerable side effects occur, or you are unable to follow study directions.

Study Visits

On **Day 1 of each cycle**:

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests and tumor marker testing.
- Blood (about 2 ½ teaspoons) will be drawn for biomarker research tests, including genetic testing.
- Urine will be collected for routine tests.
- On Day 1 of odd-numbered cycles starting with Cycle 3, you will have a CT scan or MRI to check the status of the disease.

On **Day 15 of every cycle**, blood (about 2 ½ teaspoons) will be drawn for routine and biomarker tests.

One (1), 3, and 5 weeks after surgery, blood (about 2 ½ teaspoons) will be drawn for biomarker research tests, including genetic testing.

If you can become pregnant, you will have a pregnancy test at any time that the study doctor thinks it is needed.

End-Of-Treatment Visit

Within 28 days after your last dose of study drugs:

- You will have a physical exam.
- Blood (about 1 tablespoon) will be drawn for routine tests and tumor marker testing.
- Urine will be collected for routine tests.

Follow-Up Visits

You will be followed for 2 years after your last study drug dose**. Every 3 months** after your last dose of study drugs, the study staff will review public records and/or call you to check on how you are doing. If called, this phone call should take about 5 minutes.

If you stopped receiving the study drugs for any reason other than the disease getting worse, you will also have a CT scan or MRI to check the status of the disease according to your standard of care.

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.

Gemcitabine, nab-paclitaxel, and durvalumab 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.

Gemcitabine Side Effects

Common (occurring in more than 20% of patients)

• fever • skin rash • nausea/vomiting • low blood cell counts (red, white, platelets)	• abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes)	• abnormal kidney test (possible kidney damage) • blood in the urine • difficulty breathing

Gemcitabine may cause bleeding from the gums, nose, or mouth, bleeding that would not stop, reddish or pinkish urine, and unexpected bruising.

Occasional (occurring in 3-20% of patients)

• swelling (such as arm/leg/fingers/feet/ face) • headache • difficulty sleeping • abnormal sensation (such as pins and needles)	• fatigue • hair loss (partial or total) • itching • sweating • mouth blisters/sores (possible difficulty swallowing) • constipation	• diarrhea • loss of appetite • abnormal urine tests • back pain • flu-like symptoms • injection site swelling, pain, and/or heat • infection

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

• low blood pressure (possible dizziness and/or fainting) • irregular heartbeat • heart attack • heart failure • multiple blood clots (possible organ dysfunction and/or failure) • abnormal blood clotting (increased platelet cell count) • blood vessel inflammation (possible bleeding and/or bruising)	• large skin blisters • decay of body tissue • skin scaling, ulceration, blisters • severe sunburn-like rash at site of previous radiation (called radiation recall) • destruction of red blood cells (possible kidney damage and/or failure) • leakage of fluids from blood vessels into surrounding tissue (possible difficulty breathing) • liver damage and/or failure (possibly due to	• scarring of the lungs/air sacs of the lung • wheezing • lung inflammation/ damage (possible difficulty breathing) • fluid in the lung (possible difficulty breathing) • difficulty breathing due to narrowing of the airways • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

• brain injury that may be reversible (possible headache, confusion, seizures, and/or vision loss) • stroke	blood clots and/or scarring) • kidney failure	• severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Gemcitabine may cause brain injury that may result in headache, confusion, seizures, and/or vision loss. It is not known how often this may occur.

Nab-Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • swelling • fatigue • fever • nerve damage (possible numbness, pain, and/or loss of sensory/motor function)	• hair loss (partial or total) • skin rash • nausea/vomiting • diarrhea • dehydration • loss of appetite • low blood cell counts (red, white, platelets)	• abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • weakness • pain • infection

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/fainting) • high blood pressure • chest pain • heart failure • sudden stopping of the heart • fast heartbeat • flushing • yellowing of the skin and/or eyes • blood clots in a vein (possible pain, swelling, and/or redness) • headache • depression	• low blood levels of potassium (possible weakness and/or muscle cramps) • constipation • abnormal taste • intestinal blockage • inflammation of the intestines • inflammation of the bile duct • mouth blisters/sores (possible difficulty swallowing) • vision problems • swelling under the central part of the eye (vision loss)	• difficulty breathing • lung inflammation (possible difficulty breathing) • blood clots/blockage in the lung (possible pain, shortness of breath, and/or failure to breathe) • cough • nosebleed • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure) • severe life-threatening infection (possible low blood pressure, kidney

	• abnormal kidney test (possible kidney damage)	failure, and/or heart failure)

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

• swelling (face) • irregular/slow heartbeat • decreased blood supply to the heart • heart attack or other severe heart problems • stroke and/or temporary stroke symptoms • paralysis of nerves controlling the head and neck • decreased brain function due to liver damage • difficulty walking • difficulty spelling • fainting • dizziness • shaking • restlessness • fingernail pain/discomfort • loss of fingernails • hives • skin sores • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract) • hand-foot syndrome (palms of hands/soles of feet having pain,	• sweating/night sweats • small bleedings in your skin due to blood clots • severe sunburn-like rash at site of previous radiation (called radiation recall) • bruising • low blood levels of phosphate (possible bone damage) • low blood levels of albumin (possible swelling, weakness, and/or fatigue) • low blood levels of • calcium (possible weakness and/or cramping) • low blood levels of sodium (possible headache, confusion, seizures, and/or coma) • low blood sugar • high blood sugar (possible diabetes) • inflammation of the pancreas (possible abdominal pain) • hole in the intestines (possibly leaking contents into the abdomen) • increased thirst • gas • stomach cramps	• painful and/or frequent urination • blood in the urine • loss of bladder control • decreased blood flow to part of the bowel (possibly causing tissue death) • paralysis of the intestines • liver damage and/or failure • decreased/lack of reflexes • involuntary movements • nerve pain • blurry vision • irritated/red/itchy eyes • double vision • damage to an eye nerve • collapsed lung (possible difficulty breathing) • pain (ear/skin/breasts) • ringing in the ears • lung damage at the site of prior radiation • paralysis of the vocal cords • runny nose • dry nose • pain/swelling of the nose • pain at the site of the tumor/tumor death • skin infections • infection due to the catheter line

swelling, and blistering) • red skin from sunlight • skin discoloration (including white spots on the skin)	• painful/sore gums • rectal bleeding	

Oleclumab Side Effects

This is an early study of oleclumab in humans, so the side effects are not well known. Based on early human studies and the way oleclumab is designed to work and similar drugs, oleclumab may cause:

• worsening of pre-existing heart or blood vessel disease • fatigue • fever • large blisters of the skin, mouth, and mucous membranes • blood clots in a vein (possible pain, swelling, and/or redness) • nausea/vomiting • diarrhea • loss of appetite	• low red blood cell count • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • calcium deposits on the tendons, ligaments, and/or joints (possible aches, cramps, tiredness, tingling, and/or burning pain in the legs)	• immune reaction (such as rash, fever, and joint point) • allergic reaction (such as skin rash, hives, lip/mouth swelling, difficulty breathing, and/or low blood pressure) • infection • infusion reaction (fever, shaking, chills, flushing, itching, changes in heart rate and blood pressure, difficulty breathing, and/or skin rash) •

If you have recently been treated with drugs that inhibit the growth of blood vessels (such as vascular endotheltial growth factor [VEGF] inhibitors, you may be at risk of decreased supply of blood to a body part (such as the heart or brain). The study doctor will talk to you about what these drugs are, as well as what symptoms you should watch out for.

It is important to tell the study doctor if you have a history of heart or blood vessel disease (such as chest pain, high blood pressure, irregular heartbeat, heart attack, or stroke). Oleclumab may cause these diseases to worsen.

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 • skin rash • 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) • constipation • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes)	• pain (such as muscle/joint) • lung inflammation (possible difficulty breathing) • cough • infections (upper respiratory infections, pneumonia, influenza, dental and oral soft tissue infections, oral thrush)

Occasional (occurring in 3-20% of patients)

• swelling (arms/legs) • fever • voice disorder/hoarse voice • night sweats • itching • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • loss of appetite • inflammation of the intestines • diarrhea • abdominal pain • nausea/vomiting • dehydration • difficult and/or painful urination	• low blood cell count (red, white) • liver damage/inflammation (hepatitis) • kidney inflammation or injury (possible kidney failure or decreased kidney function) • difficulty breathing

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

• inflammation of the heart (or the membrane surrounding the heart) • inflammation of the brain or membranes around the spinal cord	• pituitary gland failure/inflammation (possible headaches, thirst, and/or irregular periods in women)	• inflammation and weakness of multiple muscles • inflammation inside/around the eye

and brain (possible headache and/or coma) • immune system damage to the nervous system (causing weakness, numbness and/or paralysis) • inflammation of blood vessels • hardening/tightening of the skin and connective tissue • inflammation of skin (dermatitis) or patches of skin color loss • skin blisters • decreased production of adrenal hormones (possible weakness and/or low blood pressure)	• type 1 diabetes which requires insulin • high blood sugar • hole in the intestines (possibly leaking contents into the abdomen) • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • low platelet count • immune response (causing joint, tissue, and/or organ damage)	(possible vision problems) • immune reaction (possible loss of drug function) • lung damage • infusion reaction (possible chills, fever, difficulty breathing, and/or change in blood pressure) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • allergic reaction or over-activated immune system causing swelling of face, lips, or throat, fever, or shortness of breath

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 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.

Certain side effects caused by the investigational therapies (durvalumab and oleclumab) or their combination with the chemotherapy drugs (gemcitabine and nab-paclitaxel) may delay your scheduled surgery to remove the tumor or make you ineligible to have surgery. The study doctor can explain this possibility in more detail.

Other Risks

Having **biopsies** 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/aspiration site.

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

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

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.

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 while on study and for at least 3 months (men) or 6 months (women) after your last dose of study drug(s). Highly effective methods of birth control (those with a failure rate of less than 1%) must be used. You should discuss these with the study doctor.

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 will result in your removal from this study.

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.

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. Brandon Smaglo, at 713-792-2828) 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. It may be dangerous to suddenly stop study treatment, and the study doctor can discuss ways to safely withdraw. If you withdraw from this study, you can still

choose to be treated at MD Anderson.

The study staff may ask if they can continue collecting the results of routine care from your medical record.

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.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, 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 sponsored and/or 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. Samples will not be sent to AstraZeneca.

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

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

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.

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
- 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 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 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. 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.

_____ _____
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

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.

_____	_____	_____
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.)