THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Immunomodulation of the tumor microenvironment in high-grade serous ovarian cancer patients receiving pembrolizumab and lenvatinib monotherapy and combination therapy

2020-1121

Study Chair: Amir Jazaeri, 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 pembrolizumab and lenvatinib, when given either alone or together, can have a positive effect on the immune systems of patients with high-grade serous ovarian cancers. The safety of the drugs and their effects on the disease will also be studied.

This is an investigational study. Pembrolizumab and lenvatinib are both FDA approved and commercially available for the treatment of several types of cancer. They are not FDA approved or commercially approved to treat high-grade serous ovarian cancer. The study doctor can explain how the study drugs are designed to work.

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.

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.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Pembrolizumab and lenvatinib will be provided at no cost to you.

You may receive the study drugs for as long as the study doctor thinks it is in your best interest.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard of care treatment or another investigational therapy if available. The study doctor will discuss with you the possible risks and benefits of these treatments. 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 cancer-related symptoms.

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.
- Blood (about 3 tablespoons) will be drawn for routine tests, to check for diseases like hepatitis, and to check for a tumor marker called CA 125. Tumor markers like CA 125 may be related to the status of the disease. If you can become pregnant, part of this blood sample will be used for a pregnancy test. To take part in this study, you must not be pregnant.
- Urine will be collected for routine tests.
- You will have an EKG and an echocardiogram (ECHO) to check your heart function.
- You will have MRIs or CT scans to check the status of the disease.
- You will have a core tumor biopsy to check the status of the disease and for research tests, including genetic biomarkers. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. To perform a core biopsy, a sample of tissue is removed using a hollow core needle that has a cutting edge.

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 cohorts. This is done because no one knows if one cohort is better, the same, or worse than the other:

- If you are in **Cohort A**, you will receive a 21-day cycle of pembrolizumab by itself. You will then receive pembrolizumab and lenvatinib.

- If you are in **Cohort B**, you will receive a 21-day cycle of lenvatinib by itself. You will then receive pembrolizumab and lenvatinib.

You will have an equal chance (50/50) of being assigned to either cohort.

Up to 16 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration
The first cycle, in which you receive only one of the study drugs, will be Cycle 0. The following cycles, in which you receive both study drugs, will be Cycles 1, 2, and so on. Each cycle will be 21 days (3 weeks) long.

You will receive **pembrolizumab** by vein over about 30 minutes on Day 1 of each cycle that you receive it.

You will take **lenvatinib** by mouth 1 time each day in each cycle that you receive it. Lenvatinib should be taken at about the same time each day with water and may be taken with or without food. If you miss a dose and less than 12 hours have passed since the usual time you take the study drug, take the dose as soon as you remember. If more than 12 hours have passed, do not take the dose. Wait and take the next dose as scheduled. You will be given a pill diary to record when you take each dose and if you miss a dose.

You will also be asked to measure your blood pressure every day while on study treatment and to record the results. The study doctor will discuss this with you.

You will no longer be able to take the study drugs if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.
Your participation on the study will be over after the follow-up visits.

Study Visits
During this study, peritoneal fluid (fluid from inside the abdominal cavity) will be collected for research tests (such as genetic tests and tests of the immune system) at some study visits. To ease the collection of the peritoneal fluid, you will have an intraperitoneal (IP) port placed into your abdomen before the first day of study treatment. This port will remain in place during the study and will be removed after you complete the study. You will sign a separate consent form to allow for the port's placement and removal. The study staff will discuss the procedure with you in detail.

You will have study visits on **Days 1 and 8 of Cycles 0 and 1, and then on Day 1 of every cycle after that:**

- On **Day 1 of each cycle:**
  - You will have a physical exam.
  - Blood (about 3 tablespoons) and urine will be collected for routine tests. The blood sample will also be used for CA 125 testing. If you can become pregnant, one of these samples will also be used for a pregnancy test at any point that the study doctor thinks it is needed.

- On **Days 1 and 8 of Cycles 0 and 1, and then on Day 1 of Cycles 2, 3, 5, and every 3 cycles after (Cycles 8, 11, 14, and so on)**, blood (about 3 tablespoons) and peritoneal fluid will be collected for research tests.
- On **Day 1 of Cycles 1 and 4, and then every 4 cycles after that (Cycles 8, 12, 16, and so on)**, you will have MRIs or CT scans to check the status of the disease.
- **At any time that the study doctor thinks it is needed**, you will have an EKG and/or ECHO.

End of Treatment

Within 30 days of the last dose of the study drugs:

- Blood (about 3 tablespoons) and peritoneal fluid will be collected for research tests. Blood (about 1 tablespoon) will be drawn for CA 125 testing.
- You will have MRIs or CT scans to check the status of the disease.
- The port that was placed to collect peritoneal fluid will be removed.

Follow-Up

After you stop receiving the study drugs, every 12 weeks:

- You will have a physical exam.
- Blood (about 3 tablespoons) and urine will be collected for routine tests. The blood sample will also be used for CA 125 testing.
- If you stopped taking the study drugs for reasons other than the disease getting worse, you will have MRIs or CT scans to check the status of the disease.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. 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 affects you may have, even if you do not think they are related to the study drugs/procedures.

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

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

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

• fatigue • fever • skin rash and/or itching • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • loss of appetite • nausea • constipation • diarrhea • abdominal pain	• low blood cell counts (red, white, platelets) • abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough • difficulty breathing

Occasional (occurring in 3-20% of patients)

• swelling (face/arm/leg) • inflammation of the tissue around the heart (possible chest pain) • irregular heartbeat • headache • confusion • patches of skin color loss • underactive thyroid gland (possible weight gain, heart failure, and/or constipation)	• overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating) • low blood sugar • weight loss • fluid in the abdomen • blood in the urine • vomiting • abnormal liver test (possible yellowing of the skin and/or eyes)	• weakness • nerve damage (possible numbness, pain, and/or loss of motor function) • difficulty breathing (possibly due to lung inflammation) • flu-like symptoms • infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing)

Frequency Unknown

• heart failure • heart attack • build-up of fluid around the heart (possible heart failure)	• abnormal connections or passageways between organs or vessels • bleeding in the rectum and/or uterus	• blockage in the lung (possible pain and/or shortness of breath) • nosebleed • coughing up blood

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

• low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart • blood vessel inflammation (possible bleeding and/or bruising) • seizure • immune system damage to the nervous system (causing muscle weakness, numbness and/or paralysis) • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or with ulcers of the skin and digestive tract)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis) • inflammation/scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver), which may cause liver damage, stomach pain, yellowing of the skin/eyes, fatigue, and/or itching	• inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure) • kidney failure • build-up of fluid around the lungs • immune response that causes the body to attack itself (possible organ damage) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)

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

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue. These side effects can affect more than one of your normal organs and tissues at the same time.

Lenvatinib Side Effects

Common (occurring in more than 20% of patients)

• high blood pressure • swelling (arm/leg) • fatigue • headache • voice changes • hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering) • skin rash	• underactive thyroid gland (possible weight gain, heart failure, and/or constipation) • weight loss • diarrhea • loss of appetite • mouth blisters/sores (possible difficulty swallowing)	• nausea • vomiting • constipation • abnormal kidney test (possible kidney damage) • bleeding • pain • cough

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/fainting) • abnormal EKG • blood clots in an artery (possible organ damage such as stroke and/or heart attack) • dizziness • difficulty sleeping • hair loss (partial or total) • skin thickening • dehydration • low blood sugar	• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • high blood levels of fat (possible heart disease and/or stroke) • abnormal taste • dry mouth • upset stomach	• abnormal digestive blood test (possible inflammation of the pancreas) • abnormal liver tests (possible liver damage and/or yellowing of the skin and/or eyes) • decreased kidney function • nosebleed • fluid in the lung (possible difficulty breathing) • blockage in the lung (possible pain and/or shortness of breath)

The drug may cause an increased risk of infection, such as pneumonia or mouth infection. This infection may occur anywhere. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

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

• severe heart problems	• brain injury that may be reversible (possible headache, confusion, seizures, and/or vision loss)	• abnormal connections or passageways between different parts of the digestive system

		• low platelet counts • collapsed lung (possibly difficulty breathing)

Lenvatinib may also increase the risk of bleeding from tumor sites in patients with anaplastic thyroid cancer. This bleeding may be serious and could result in death. This study may involve unpredictable risks to the participants.

Events of osteonecrosis of the jaw (ONJ – bone destruction in the jaw) have been seen in patients who have received lenvatinib. Invasive dental procedures are a risk factor for the development of ONJ. You should consider having a dental exam and appropriate preventive dentistry before you start receiving lenvatinib. The study doctor will give you more advice about periodic dental exams and oral hygiene practice while you are receiving the drug. Avoid invasive dental procedures during lenvatinib treatment, if possible.

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.

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 and ECHOs 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 biopsy. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

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. Only authorized study staff will have access to study data.

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 or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active.

Acceptable forms of birth control include:

- barrier methods (such as cervical cap, sponge, or diaphragm, and each of these methods need to be used with spermicide),
- intrauterine device (IUD), or
- hormonal birth control that contains estrogen and/or progestin (such as birth control pills, patch, shot, or implant).

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.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a tumor biopsy at the End of Treatment visit. The study doctor will tell you what type of biopsy you will have and its risks. The tissue sample will be stored in a research bank at MD Anderson for use in future research related to cancer and/or other disease.

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. Only individuals with IRB permission and designated bank staff 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. Additionally, if needed for certain types of research in the future and if the IRB approves, the bank staff and approved research staff will be able to link your samples back to you.

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned. 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

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 site.

MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy but cannot guarantee complete privacy.

If you withdraw your consent to the storage of samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

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

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

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

Optional Procedure #1: Do you agree to have a tumor biopsy at the End of Treatment visit and allow the tissue to be stored in a research bank at MD Anderson for use in future research related to cancer and/or other diseases?

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, Eisai, or Merck 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. Amir Jazaeri, at 713-745-1613) 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. 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. You may be asked whether the study doctor can continue to collect data from your routine medical care. 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, Merck, Eisai, 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 supported by: Merck and Eisai.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter(s). 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, Eisai, and Merck, 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. Merck or Eisai will not receive samples for future research.

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 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 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.

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

Genetic 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

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

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)

- The IRB and officials of MD Anderson
- Merck and Eisai, who are 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.

To protect your identity, the samples collected from you will be labeled a unique number instead of your name or other identifying information. Only the study doctor or study staff will have access to the code that can link you to your samples.

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.)