THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Phase 2 Study of PI3K Inhibitor Copanlisib in Combination with Fulvestrant in ER+ and/or PR+ Cancers with PI3K (PIK3CA, PIK3R1) and/or PTEN Alterations
2020-1241

Subtitle: Copanlisib and Fulvestrant- Protocol V2.0

Study Chair: Timothy A. Yap

_____ _____
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 copanlisib in combination with fulvestrant can help to control advanced solid tumors.

This is an investigational study. Copanlisib and fulvestrant are each FDA approved and commercially available for the treatment of certain types of cancers but may not be approved for the type of cancer you have. The study doctor will tell you if copanlisib and/or fulvestrant are approved for the treatment of the type of cancer you have. It is considered investigational to give copanlisib and fulvestrant together to help control advanced solid tumors.

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

Copanlisib will be provided to you at no cost during the study. You and/or your insurance provider will be responsible for the cost of fulvestrant and for the costs related to receiving the study drugs.

You may continue receiving copanlisib and fulvestrant for as long as the study doctor thinks it is in your best interest. 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.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive alternate therapies that are approved for treatment of your cancer (called standard of care), which may include chemotherapy and/or radiation therapy. The study doctor will discuss with you the alternative therapies that are most appropriate for your cancer, 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 be done within 28 days before your first dose of the study drugs to help the doctor decide if you are eligible.

- You will have a physical exam.
- You will have an EKG and either an echocardiogram (ECHO) or MUGA scan to check your heart function.
- Blood (about 5 tablespoons) will be drawn for routine tests, to check for infectious viruses (cytomegalovirus [CMV], hepatitis B virus [HBV], and hepatitis C virus [HCV]), and for biomarker testing (including genetic biomarkers). Biomarkers are found in the blood/tissue and may be related to your reaction to the study drugs. You must fast (have nothing to eat or drink except water) for 8 hours before blood is drawn.
- Urine will be collected for routine tests.
- You will have either an MRI or CT scan to check the status of the disease.
- If leftover tumor tissue from a previous procedure is available, it will be collected for biomarker testing, including genetic biomarkers.
- If you have recently had a tumor biopsy, the results will be collected. If you have not had a recent biopsy, you will be asked to have one to check if you are eligible to take part in this study. This is described in more detail below in the Optional Procedures for the Study section.
- If you can become pregnant, part of the above blood draw will be used for a pregnancy test. To take part in this study, you must not be pregnant.

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.

Up to 78 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration
Each study cycle is 28 days.

You will receive **copanlisib** by vein over about 60 minutes on Days 1, 8 and 15 of each cycle.

You will receive **fulvestrant** as an intramuscular injection (an injection directly into your muscle tissue) on Days 1 and 15 of Cycle 1 and then on Day 1 only of Cycles 2 and beyond.

All participants will receive the same dose of study drugs, but if you have side effects, your dose may be lowered. This will be discussed with you.

Study Visits
You will come to the clinic 1 time every week during the first cycle (Days 1, 8, 15, and 22 of Cycle 1) and then 1 time every week during the first 3 weeks of every cycle after that (Days 1, 8, and 15 of Cycles 2 and beyond). The study staff will discuss your study visit schedule with you.

On **Day 1 of all cycles**:
- You will have a physical exam.
- You will have an EKG to check your heart function
- Blood (up to 2 tablespoons) will be drawn for routine tests and/or biomarker testing, including genetic biomarkers. You must fast for at least 8 hours before blood is drawn.
- Urine will be collected for routine tests.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test.

On **Days 8, 15, and 22 of Cycle 1** and on **Days 8 and 15 of Cycles 2-4**:
- You will have a physical exam (except on Day 8 of Cycles 2-4).
- Blood (up to 2 tablespoons) will be drawn for routine tests. The study staff will tell you when you must fast for at least 8 hours before blood is drawn.

On **Day 1 of Cycle 2**:
- Blood (up to 4 tablespoons) will be drawn for routine tests and/or biomarker testing, including genetic biomarkers. The study staff will tell you when you must fast for at least 8 hours before blood is drawn.

On **Day 1 of Cycle 3 and every odd-numbered cycle after** (Cycles 5, 7, 9, and so on), you will have either an MRI or CT scan to check the status of the disease.

After you have completed the MRI or CT scan to check the status of your disease only in Cycles 3 and 5, and the study doctor thinks it is needed, blood (up to 2 tablespoons) will be drawn for biomarker testing, including genetic biomarkers.

If the study doctor thinks it is needed, some of the above tests may be done more often. This will be discussed with you**.**

During this study, you may be able to go to your primary care doctor instead of visiting the study clinic to have some of the above tests and procedures done, such as physical exams and blood draws. This will be discussed with you.

Treatment Beyond Progression

If the disease appears to be getting worse or the tumors appear to be getting larger, you may still be able to receive the study drugs if you and your doctor decide it is in your best interest. This is because sometimes the disease appears to get worse, but the study drugs are actually working.

However, there are risks of continuing to receive the study drugs. For example, the disease may actually be getting worse and may reach the point that you are no longer able to receive other treatments. You are still at risk for side effects due to the study drugs. This could also delay starting other treatments.

If you choose to receive the study drugs after the disease appears to get worse, you will continue to have study visits as described above. The study doctor will discuss this option with you.

End-of-Dosing Visit

Within 28 days after your last dose of study drugs:

- You will have a physical exam.
- Blood (about 2 tablespoons) will be drawn for routine tests and biomarker testing, including genetic biomarkers.
- Urine will be collected for routine tests.
- You will have either an MRI or CT scan to check the status of the disease.

Follow-Up Period

Safety Follow-Up Visit

About 30 days after your last dose of study drugs, you will be asked about any side effects. If any side effects have not resolved at this time, you may have additional safety follow-up. This will be discussed with you.

Long-Term Follow-Up

If you stop taking the study drugs for reasons other than the disease getting worse, you will continue to have either an MRI or CT scan to check the status of the disease

every 8 weeks until you withdraw from the study, the disease gets worse, you start a new anticancer therapy, or the study ends.

If the disease gets worse, or if you start a new anticancer therapy, the study staff will call you to ask how you are doing every 12 weeks until you withdraw from the study or the study ends. Each call will take about 10 minutes.

Other Instructions

- While you are receiving the study drugs, avoid having any grapefruit, grapefruit juice, and products containing juices of this fruit.
- Do not take any supplements that contain St. John's Wort.
- Tell the study doctor about all medications (including non-prescription medicines, herbal remedies, vitamins, and supplements) you are taking before starting the study, while you are on the study, and for 30 days after your last dose of study drugs. Do not take additional medications without talking to the study doctor. Some medications and herbal supplements are not allowed because they may affect how the study drugs work.

COVID-19 Study Changes

Because of the COVID-19 pandemic, changes may be made to how the study is performed. All changes will be discussed with you.

Telemedicine: Some of the study visits normally done at the clinic may instead be done over the telephone or video conferencing. The study staff will tell you when/if this is an option and explain how these conversations will remain private and confidential.

Delayed Assessments: Some of the required procedures may be done at different times than originally planned.

Remote Monitoring: The MD Anderson Investigational New Drug (IND) office will check on the conduct of the study and will review your study records and your medical records during these monitoring visits. Your records may also be reviewed remotely via secure methods by the MD Anderson IND office or its representatives.

You should discuss with your study doctor whether participating in this study is right for you during the COVID-19 pandemic.

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 the study drugs are 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 the study drugs. 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.

Copanlisib and fulvestrant 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.

Copanlisib Side Effects

Common (occurring in more than 20% of patients)

• high blood pressure • fatigue • high blood sugar that may be severe (possible diabetes) • low blood levels of phosphate (possible bone damage)	• high blood levels of fat (possible heart disease and/or stroke) • high blood levels of uric acid (possible painful joints and/or kidney failure)	• diarrhea • nausea • abnormal digestive blood test (possible inflammation of the pancreas) • low blood cell counts (red, white, and/or platelet)

Occasional (occurring in 3-20% of patients)

• painful or abnormal skin sensations • abnormal sensation (such as pins and needles)	• skin rash • mouth blisters/sores (possible difficulty swallowing) • vomiting	• lung inflammation (possible difficulty breathing)

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

• shedding and scaling of the skin (possible fatal loss of bodily fluids)

Fulvestrant Side Effects

Common (occurring in more than 20% of patients)

• fatigue • nausea • diarrhea	• low blood cell counts (red, white) • abnormal liver tests (possible liver damage)	• infection

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • hot flash • headache • dizziness • fever • hair loss (partial or total) • skin rash/itching • low blood sugar • low blood levels of albumin (possible swelling, weakness, and/or fatigue)	• low blood levels of phosphate (possible bone damage) • loss of appetite • vomiting • constipation • mouth blisters/sores (possible difficulty swallowing) • abnormal taste • abdominal pain	• low platelet blood cell count • pain • weakness • cough • difficulty breathing • injection site pain

Frequency Unknown

• pain shooting from the lower back to the thighs • nerve pain	• nerve damage (possible numbness, pain, and/or loss of motor function)	• abnormal kidney test (possible kidney damage)

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

• blood clot in a vein (possible pain, swelling, and/or redness)	• uterine and/or vaginal bleeding	• liver damage • liver failure

<u>Study Drug Combination Side Effects</u>

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

<u>Other Risks</u>

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

MUGA scans may cause allergic reactions to the radioactive tracer, injection site soreness, and/or swelling. They may cause damage to cells or tissue from being

exposed to the radiation used in the scan. These side effects may occur in less than 10% of patients.

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, which may create a need for blood transfusions.

Fasting may cause your blood sugar to drop. You may feel tired, hungry, and/or nauseous. If you have diabetes, it is important to talk to your doctor about managing your blood sugar while fasting.

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.

During an **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 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.

If an MRI contrast material is used, your study doctor will tell you about possible side effects or allergic reaction. Contrast agents can cause allergic reactions and kidney damage. Allergic reactions can include mild itching associated with hives but can also result in a serious life-threatening emergency from difficulty breathing. If this occurs, it is treatable. 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.

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.

Females: If you can become pregnant and are sexually active, you must use 2 highly effective methods of birth control during the study and for at least 150 days after your last dose of study drugs. Highly effective birth control methods include:

- Combined (estrogen- and progestogen-containing) hormonal birth control pills, patches, or intravaginal methods
- Progestogen-only hormonal birth control pills, injections, or implants
- Intrauterine device (IUD) or intrauterine hormone-releasing system (IUS)
- Bilateral tubal occlusion (surgical sterilization also known as “tubes tied”)
- Vasectomized partner (with the absence of sperm confirmed) as your only male sexual partner

If you use a hormonal birth control method, it should be used in combination with a barrier method (such as condoms). The study doctor will discuss with you what methods to use during this study and how to use them.

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.

Males: If you can father a child and are sexually active, you must use a barrier method (such as a condom with spermicidal foam/gel/film/cream/suppository) during the study and for at least 90 days after your last dose of study drugs. If your partner can become pregnant, they must also use 1 of the above highly effective birth control methods during this time. If you have had a vasectomy more than 6 months before signing this consent form, you may not need to use a barrier method. The study doctor will discuss with you what methods to use during this study and how to use them.

Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a tumor biopsy at screening (if you have not had a recent biopsy), on Day 1 of Cycle 2, and at the End-of-Dosing Visit for biomarker testing, including genetic biomarkers. The results of the biopsy at screening will be used to check if you are eligible to take part in this study. The study doctor will tell you what type of biopsy you will have.

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 in the optional procedure 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, 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

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

Optional Procedure #1: Do you agree to have a biopsy at screening (if you have not had a recent biopsy), on Day 1 of Cycle 2, and the End-of-Dosing Visit?

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 Bayer Healthcare 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. Timothy A. Yap, at 713-563-1930) 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. You may be asked whether the study doctor can 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, Bayer Healthcare, 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, or if you are unable to follow study directions.

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.

   Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

   However, you will not receive the results from biomarker and PK testing because they are being done for research purposes only.

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

study.

9. This study is supported by: Bayer Healthcare.

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 Bayer Healthcare 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. Leftover samples will not be stored by or used in future research by Bayer Healthcare.

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.

Outside Care

Part of your care may be provided outside of MD Anderson by your home doctor(s).

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:

- Timothy A. Yap (Study Chair)
- Shannon Westin (Co-PI)

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

- Bayer Healthcare, who is a supporter of this study, and/or any future sponsors/supporters and/or licenses 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.

The supporter, Bayer Healthcare, may transfer your study data to countries outside of the United States for the purposes described in this form. Please be aware that the laws in such countries may not provide the same level of data protection as in the US and may not stop your study data from being shared with others. All data that are transferred will be coded. The study doctor, the regulatory authorities, and the sponsor may keep the research records forever.

Tissue, blood, CT scans, MRI scans, and other test results may be submitted to a third party for review.

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.)