THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase 2, Study of Apalutamide and Abiraterone Acetate in Castration-Resistant Metastatic Prostate Cancer Patients Evaluating a Predetermined Biomarker Signature
2017-0060

Study Chair: Bagi R. Jana

_____ _____
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 apalutamide in combination with abiraterone acetate and prednisone can help to control metastatic (has spread) castration-resistant prostate cancer (mCRPC) that has a certain type of biomarker in the tumor. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug(s).

This is an investigational study. Apalutamide is FDA approved and commercially available for the treatment of non-metastatic castration-resistant and metastatic castration-sensitive prostate cancer (mCSPC). It is currently being used for research purposes. The combination of abiraterone acetate and prednisone is FDA approved and commercially available for the treatment of mCRPC and metastatic high-risk castration sensitive prostate cancer.

The study doctor can explain how the study drugs are designed to work.

The study drugs may or may not 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 (such as high blood pressure, fatigue, constipation, skin rash, low red blood cell count, weight gain, mood swings, difficulty sleeping, and/or muscle loss), potential expenses, and time commitment/prolonged stay out of town (1-3 days in Houston).

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

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

Apalutamide and abiraterone acetate will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the cost of prednisone.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard chemotherapy. You may choose to receive other investigational therapy, if available. The study doctor will discuss 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 symptoms of cancer.

1. STUDY DETAILS

Up to 60 participants will be enrolled in this study. All will take part at MD Anderson.

Screening Tests

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

- You will have a physical exam.
- You will have an EKG and an echocardiogram (ECHO) or MUGA scan to check your heart function.
- You will have an MRI, and a bone scan to check the status of the disease., you may also have a chest CT scan.
- Blood (about 6-7 teaspoons) will be drawn for routine tests and tests to check your prostate specific antigen (PSA) and testosterone levels.
- If available, a leftover tumor tissue sample will be collected for biomarker testing, including genetic biomarkers. If no leftover tissue is available, a tumor biopsy will be performed. The type of biopsy you have will depend on where the disease has spread and/or what the doctor thinks is in your best interest. The doctor will discuss with you the type of biopsy you will have.

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 Drug Administration
Each study cycle is 28 days.

If you are found to be eligible to take part in this study, you will take 4 apalutamide tablets by mouth 1 time at about the same time each day with or without food.

You will take 4 abiraterone acetate tablets by mouth 1 time at about the same time every day. Do not eat for at least 2 hours before your dose and for at least 1 hour after the dose of abiraterone acetate.

You will take prednisone by mouth 1 time every day. You can take the dose with or without food, but it is recommended that you take prednisone with a meal.

You may take these tablets together, when possible. All tablets should be swallowed whole and not crushed or chewed.

If you overdose (take 2 days of study drugs or more in 24 hours), contact the study doctor right away.

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after the follow-up visit.

Study Visits

On Day 1 of Week 1:
- You will have a physical exam.
- Blood (about 6-8 teaspoons) will be drawn for routine testing, to check for genetic mutations (changes), and for thyroid, ACTH, and hormone testing. ACTH and hormone testing is done to help check on your health as well as help the doctor decide if your prednisone dose should be changed. Also, if you consent to take part in another study at MD Anderson, LAB02-152 blood will be drawn and stored for future research. If you do not sign the consent form for LAB02-152, this blood draw will not be performed.

On **Day 1 of Week 4 and then every 4 weeks starting at Week 9** (Weeks 13, 17, 21, and so on):
- You will have a physical exam
- Blood (about 3-4 teaspoons) will be drawn for routine testing and to check your PSA levels. During Week 9, this sample will also be used to check your testosterone levels.

On **Day 1 of Week 5 and every 4 weeks after that** (Weeks, 9, 13, 17 and so on
- Blood (about 6-8 teaspoons) will be drawn for, ACTH, and hormone testing.

- During Week 9 only, blood (about 6-8 teaspoons) will be drawn and stored for future research. This blood draw will only be performed if you consent to take part in another study at MD Anderson, LAB02-152. If you do not sign the consent form for LAB02-152, this blood draw will not be performed.

On **Day 1 of Week 13 and every 12 weeks after that** (Weeks 25, 37, 49, and so):

- Blood (about 3 teaspoons) will be drawn for routine testing, thyroid and hormone testing.
- At Week 13 only, you will have an MRI, and a bone scan to check the status of the disease. you may also have a chest CT scan.

End-of-Treatment Visit

As soon as possible after your last dose of study drugs:

- You will have a physical exam.
- Blood (about 3-4 teaspoons) will be drawn for routine testing and to check your PSA and testosterone levels.
- You will have a CT scan or MRI.

Follow-Up Visit

Within 30 days after your last dose of study drug:

- You will have a physical exam.
- You will have an EKG.
- Blood (about 3 teaspoons) will be drawn for routine tests.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures. These side effects may include seizures or skin rash that is painful or has blisters near the lips, eyes, or genitals. Tell the doctor right away if you think you have had a seizure or passed out. Your doctor will make sure you are not taking any drugs that may increase the risk of having a seizure.

Apalutamide Side Effects

Common (occurring in more than 20% of patients)

• high blood pressure • fatigue • skin rash (possibly near the lips, eyes, and/or genitals) • hot flashes • high blood sugar (possible diabetes)	• underactive thyroid gland (possible weight gain, and/or constipation) • high blood levels of fat (possible heart disease and/or stroke)	• high blood levels of potassium (without signs of kidney failure/damage) • low blood cell count (red, white)

Apalutamide may cause a low blood cell count (red 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 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.

Occasional (occurring in 3-20% of patients)

• swelling (arms/legs) • decreased blood supply to the heart • falls • hair loss	• itching • diarrhea • nausea • abnormal taste / taste changes	• loss of appetite • joint pain • weight loss • broken bone(s) • muscle spasms

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

• seizure • heart failure • stroke • Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)--skin rash (possible fever/ lymph node swelling/ inflammation of internal organs/ abnormal blood cell counts)	• very severe blistering skin disease (loss of large portion of skin), which may be life-threatening • restless leg syndrome (an uncontrollable urge to move your legs due to discomfort)	• lung inflammation (possible difficulty breathing), which may cause permanent lung damage

<u>Abiraterone Acetate Side Effects</u>

Common (occurring in more than 20% of patients)

• swelling (whole body/ arm/leg)	• abnormal salts, minerals, and/or	• diarrhea

• high blood pressure • fatigue • hot flashes • high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke)	acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • constipation	• abnormal liver test (possible liver damage, yellowing of the skin and/or eyes) • pain (joint /muscle/bone) • joint swelling

Abiraterone acetate may commonly cause low white blood cell counts. 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.

If you have diabetes and you take abiraterone acetate in combination with prednisone/prednisolone and diabetes medication (such as pioglitazone or repaglinide), your blood sugar may drop.

Occasional (occurring in 3-20% of patients)

• irregular/fast/slow heartbeat • chest pain (possibly due to heart trouble) • walking/balance problems (possible falling)	• fever • difficulty sleeping • skin rash • upset stomach • frequent urination (possibly at night) • blood in the urine	• groin pain • broken bones • cough • difficulty breathing

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

• abnormal EKG • heart failure • enlarged heart • shock caused by heart damage	• decreased production of adrenal hormones (possible weakness and/or low blood pressure)	• decreased bone density (loss of bone strength) • muscle weakness

Women who are pregnant or who may be pregnant should wear gloves if they need to touch abiraterone acetate tablets.

<u>Frequency unknown</u>

• fast/irregular heartbeat (called	• liver failure	• lung inflammation (possible difficulty breathing)

Torsades de Pointes)	• breakdown of muscle tissue (it can cause kidney failure)	

Prednisone Side Effects

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

• enlarged heart • heart failure • high blood pressure • swelling (such as of the face) • headache • increased pressure between the skull and brain (possible headaches, vision changes, and/or mental status changes) • weakness • difficulty sleeping • mood swings • euphoria (unusual feelings of happiness or well-being) • personality changes • depression • seizure • fatigue/lack of energy • fatigue and anxiety • dizziness • bruising • nervousness • tiny dots on the skin • skin tests (such as for TB) may not be accurate • redness (face) • hair growth • thin fragile skin • hives	• Cushing's syndrome (possible weakness, diabetes, and/or bone weakness) • stunted growth • decreased ability to process carbohydrates • high blood sugar (possible diabetes) • diabetes • abnormal blood acid/base balance (possible organ damage) • body-wide loss of proteins (possible weakness and/or swelling) • low blood levels of potassium (possible muscle cramps) • high levels of salt in the body (possible swelling) • abnormal blood acid/base balance (possible organ damage) • abdominal swelling • inflammation of the pancreas (possible abdominal pain) • weight gain • increased appetite • indigestion • nausea	• esophagus sore • abnormal liver or bone tests (possible liver damage) • changes to the menstrual cycle • joint pain • pain or loss of function of the hips and/or shoulders due to bone death • muscle weakness • loss of bone strength (possible broken bones) • broken bone(s) • decreased muscle mass • muscle damage causing weakness • tendon tear • increased pressure in the eye (possible vision loss, pain, and/or blurry vision) • cataracts (clouding of the lens of the eye) • eye irritation • swelling (eyelid) • nosebleed • allergic reactions that may be life-threatening (such as difficulty breathing, low blood pressure, and/or organ failure)

• sweating • wound healing problems	• stomach ulcer	

Rarely (in fewer than 3% of patients)

• blood clots in a vein (possible pain, swelling, and/or redness)

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

Prednisone may cause you to develop another type of cancer (such as Kaposi's sarcoma).

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.

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.

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.

X-rays send a small amount of radiation though the body. All radiation adds up over a lifetime and may increase the risk of a new cancer forming.

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.

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

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 baby, so you must use birth control during the study if you are sexually active.

Birth Control Specifications: If your partner is able to become pregnant, you and your partner must be willing to use 2 methods of birth control from screening until 12 weeks after your last dose of study drug. Check with your study doctor about what kind of birth control methods to use. The 2 methods must consist of a condom and the use of another barrier method (such as a diaphragm or cervical/vault caps) with a spermicidal agent. Your female partner can choose to use an intrauterine device or system (IUD or IUS) or use birth control pills, injections, or implants instead of a barrier method.

Males: Do not donate sperm during the study and for up to 12 weeks after your last dose of study drug. Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, tumor tissue that is left over from your diagnosis and/or other tests performed outside of this study will be collected and stored in a research tissue bank at MD Anderson for use in future research related to cancer.

Optional Procedure #2: If you agree, blood and tissue that is left over from the tests performed on this study will be stored in a research tissue bank at MD Anderson for use in future research related to cancer.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. 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.

Optional Procedure #3: If you agree and the doctor thinks it is safe, you will have a tumor biopsy for biomarker testing when you stop taking the study drugs. The study doctor will tell you what kind of biopsy you will have and its risks.

There are no benefits to you for taking part in the optional procedures. 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 procedures.

Optional Procedure Risks:
MD Anderson and others can learn about cancer and other diseases from your **banked samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families. **Genetic research** may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to

have difficulty obtaining insurance coverage and/or a job.

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

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

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

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

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

Optional Procedure #1: Do you agree to allow leftover tumor tissue from tests outside this study to be stored in a research tissue bank at MD Anderson for use in future research related to cancer?

YES NO

Optional Procedure #2: Do you agree to allow leftover blood and tissue from tests performed on this study to be stored in a research tissue bank at MD Anderson for use in future research related to cancer?

YES NO

Optional Procedure #3: Do you agree to have a tumor biopsy for biomarker testing when you stop taking the study drugs?

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 Janssen Research & Development 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. Bagi Jana, at 713-792-2830) 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, Janssen Research & Development, 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.

The results for most of the tests required in the study will be placed in your medical record. No research-specific test results will be given to you.

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: Janssen Research & Development.

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

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

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or 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 samples are used for future research. If this 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 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.

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. Ana Aparicio (Collaborator) has received compensation from Janssen Research & Development 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
- Janssen Research & Development, 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

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO 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.)