THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Pirtobrutinib (LOXO-305) Consolidation for MRD Eradication in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Treated with Venetoclax

2021-0953

Subtitle: Pirtobrutinib + Venetoclax

Study Chair: Alessandra Ferrajoli

_____ _____
Participant's Name Medical Record Number

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

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

STUDY SUMMARY

The goal of this clinical research study is to learn if the combination of LOXO-305 (pirtobrutinib) and venetoclax can help to control previously treated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL). The safety and effects of the drug combination will also be studied.

This is an investigational study. Pirtobrutinib is not FDA approved or commercially available. It is currently being used for research purposes only. Venetoclax is FDA approved and commercially available for the treatment of CLL/SLL. It is investigational to use these drugs in combination.

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

The study drugs you receive 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, potential expenses, and time commitment. If you take part in this study, you may experience side effects, some of which may be severe or fatal. You should also know there is the possibility the disease may get worse while you are on study.

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

The study is expected to last for about 5 years, but you may continue taking the study drug(s) for as long as the study doctor thinks it is in your best interest.

Pirtobrutinib will be provided to you at no cost during this study. You and/or your insurance provider will be responsible for the cost of venetoclax.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive venetoclax and rituximab, other available treatments (such as idelalisib, bendamustine, duvelisib), or other options such as stem cell transplantation or chimeric antigen receptor T cell therapy (CAR-T). You may choose to receive other 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 symptoms of cancer. Please talk to your study doctor about your choices before you decide whether you will take part in this research study.

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 before the first dose of study drug to help the doctor decide if you are eligible:

- You will have a physical exam.
- You will have an EKG and echocardiogram (ECHO) to check your heart function.
- Urine will be collected for routine tests.
- Blood (up to 4 teaspoons) will be drawn for routine tests, to check for infectious viruses (hepatitis B and C and cytomegalovirus [CMV]), and to check the status of the disease. Positive test results for infectious viruses may be reported to your local health department as locally required.

- You will have imaging scans (such as CT scans or MRIs) to check the status of the disease.
- You will have a bone marrow biopsy and aspirate to check the status of the disease. To collect a bone marrow biopsy and aspirate, an area of the hip or other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.
- If you can become pregnant, blood (less than ½ teaspoon) or urine will be collected for a pregnancy test. If you have a positive urine pregnancy test, blood will be collected. 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 treatment options will be discussed with you.

Up to 44 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

The study cycle for each arm is 28 days.

You will take a tablet of **pirtobrutinib** by mouth at the same time each day. The tablet can be taken with or without food or drink and should be swallowed whole without breaking or chewing. Pirtobrutinib tablets should be stored at room temperature.

If you miss a pirtobrutinib dose and more than 6 hours have passed since the usual time you take the study drug, you should skip that dose and take the next dose at the scheduled time. If you vomit a dose, you should not take a make-up dose. Instead, you should take the next dose at the scheduled time.

You will take **venetoclax** tablets by mouth at the same time each day. The study doctor will tell you how many tablets to take. The tablets should be taken with food and about a cup (8 ounces) of water and should be swallowed whole without breaking or chewing.

When taking venetoclax, you will be given standard drugs to help decrease the risk of side effects of and will be monitored for your side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will no longer be able to take the study drug if side effects are too much to withstand, if you are unable to follow study directions, or if the study doctor no longer thinks it is in your best interest to continue taking the study drug. If this happens, you will have the end-of-dosing and follow-up visits described below.

Study Visits

On **Day 1 of Cycles 1-4, then every 3 cycles until the end of Cycle 12, and then every 6 months after that,** blood (about 2 teaspoons) will be drawn for routine tests. Additional tests will only be performed at certain visits:

- You will have a physical exam at **Cycles 1, 2, 4, 7, 10, 13, 19, 25 and all visits after that**.
- Blood (about 1 teaspoon) will be drawn to check status of the disease **(Cycle 4 and all visits after that)**.
- You will have imaging scans to check the status of the disease **(Cycles 7, 13, 19, and 25)**.
- If you can become pregnant, blood (less than ½ teaspoon) or urine will be collected for a pregnancy test. If you have a positive urine pregnancy test, blood will be collected to confirm the result **(Cycle 4 and all visits after that)**.

On **Day 15 of Cycle 1:**

- Blood (about 2 teaspoons) will be drawn for routine tests.

At any time if your treating doctor or the study doctor thinks it is needed, if the disease gets worse, or if the disease is no longer able to be detected in blood tests, you will have a bone marrow biopsy and aspirate at your next scheduled clinical visit to check for disease in the bone marrow using next generation sequencing (NGS). NGS identifies and measures rearranged B-cell receptors (a type of white blood cell) in DNA taken from your blood or bone marrow.

Safety Follow-Up Visit

About 4 weeks after your last dose of study drugs, if the drugs were stopped due to side effects:

- You will have a physical exam.
- Blood (up to ½ tablespoon) will be drawn for routine testing.
- If the study doctor thinks it is needed, urine will be collected for routine tests.

If the study doctor thinks it is needed, the above tests/procedures may be repeated at any time to check the status of the disease and to monitor your health. If you have an unscheduled EKG, blood (less than ½ teaspoon) will also be drawn to check your heart health.

Long-Term Follow-Up

After treatment completion or if you stop taking the study drug for any reason other than the disease getting worse, you will have follow-up visits every 24 weeks (6 months) until you withdraw from the study, the disease gets worse, you start a new treatment, or the study ends:

- You will have a physical exam.
- Blood (about 2 teaspoons) will be drawn for routine tests.
- Blood (about 1 teaspoon) will be drawn to check status of disease.
- If you can become pregnant, blood (less than ½ teaspoon) or urine will be collected for a pregnancy test. If you have a positive urine pregnancy test, blood will be collected to confirm the result.

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 pirtobrutinib and/or venetoclax 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 drug is actually working.

However, there are risks of continuing to receive the study drug(s). 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 drug(s). This could also delay starting other treatments.

If you choose to receive the study drug(s) 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.

If you choose not to receive the study drug after the disease appears to get worse, you will have the end-of-dosing and follow-up visits described above.

Other Information

You ***must*** follow the restrictions as outlined below:

- Prescription medicines, over-the-counter drugs, and herbal supplements may affect the way your body uses or gets rid of the study drug. This includes St. John's Wort and other medications. Avoid medications that are strong or moderate CYP3A inhibitors or inducers, or strong inhibitors of p-glycoprotein. The study doctor will discuss these with you. It is very important to tell the study staff about all medicines, drugs, and supplements you may be taking. Do not start taking something new during the study without discussing it with the study staff first.
- You should not consume any grapefruit, Seville (sour) oranges, star fruit, and products containing juices of these fruits from the 3 days before your first dose of the study drug until the last dose.
- You cannot receive any other investigational drug or anticancer therapies for up to 4 weeks or have had radiation therapy within 7 days (could be up to 4 weeks for certain types of radiation) before the first dose of the study drug.
- You are not allowed to receive live vaccines within 28 days before dosing and while on study.
- While taking the study drug, you are not allowed to take other investigational or anticancer drugs, receive radiation therapy, or take drugs that may weaken your immune system unless approved by the study doctor. The study doctor will tell you what medications, including some hormonal therapies used to treat some cancers, you may be allowed to continue while on study.
- Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from your study doctor.

2. POSSIBLE RISKS

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

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

Pirtobrutinib and venetoclax may each cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

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

Pirtobrutinib Side Effects

This is an early study using pirtobrutinib in humans, so the side effects are not well known. Based on early human studies, pirtobrutinib may cause:

• swelling (arms/legs) • dizziness • fatigue • fever • headache • skin rash	• nausea • constipation • diarrhea • abdominal pain • low blood cell count (red and white) • back pain	• high blood levels of uric acid (possible painful joints and/or kidney failure) • cough • shortness of breath • infections

Pirtobrutinib may cause an increase in white blood cell counts. This could rarely cause a loss of alertness, difficulty walking, headache, or bleeding (including bleeding the brain). You may need to have a procedure to decrease the number of white blood cells circulating in your blood. An increase in white blood cell count may

also mean that the disease is getting worse if it is seen with other signs of disease worsening.

Based on animal studies, pirtobrutinib may cause:

• abnormal EKG	• changes to the eye cornea (possible vision problems, pain, redness, and/or feeling of something in the eye)	• overactive immune cells in the lungs and large intestine (possible inflammation, inflammatory lesions, bleeding, tissue death, and/or fever)

Pirtobrutinib may cause loss of or harm to a developing embryo or fetus (particularly regarding the development of the kidneys, ureters [the tube by which urine passes from the kidney to the bladder], ovaries, uterus and skin).

Venetoclax Side Effects

Common (occurring in more than 20% of patients)

• swelling (arm/leg) • fatigue • high blood sugar (possible diabetes) • 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)	• diarrhea • nausea • low blood counts (red, platelets, and white) • abnormal liver tests (possible liver damage)	• muscle and/or bone pain • upper respiratory tract infection • cough

Occasional (occurring in 3-20% of patients)

• fever • headache • dizziness • skin rash • vomiting • constipation • abdominal pain • mouth blisters/sores (possible difficulty	• high blood levels of uric acid (possible painful joints and/or kidney failure) • pneumonia • difficulty breathing • severe life-threatening infection (possible low blood pressure, kidney	• bacteria in the blood • tumor lysis syndrome (TLS)--breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage,

swallowing) • joint pain	failure, and/or heart failure)	and/or other organ damage)

TLS is a problem that can occur when cancer cells break down rapidly and the body has to get rid of the broken up cell parts. Sometimes your body, especially the kidneys, cannot remove the cell parts quickly enough, so the level of some of these cell products in your blood, such as salts and acids, can rise. This can happen especially in participants with large tumors or a high number of cancerous white cells in the blood. TLS can lead to serious problems, such as effects on your kidneys and heart (including abnormal heart rhythms), seizures, or even death.

If you develop TLS, your urine may look dark, thick, or cloudy. You may have fever, chills, nausea/vomiting, diarrhea, confusion, shortness of breath, irregular heartbeat, fatigue, muscle pain, joint discomfort, and/or seizure. If you notice any of these, tell your doctor or nurse right away. Your study doctor will closely watch and treat you as needed to lower the risk of any serious changes in your blood or other complications of TLS. You may need to have extra blood tests or EKGs to check for signs of TLS.

If you notice any rash, hives, itching, or other signs of an allergic reaction such as swelling, wheezing, or you are having a hard time breathing, tell your doctor right away.

At this time, there are no known serious side effects that **occur in fewer than 3% of patients**.

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 and bone marrow biopsies/aspirates** 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 (numbing medicine) 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.

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. You must use birth control (both a barrier method and a highly active method, as defined below) during the study and for 6 months after the last dose of the study drug if you are could become pregnant or father a child and are sexually active. You should not donate sperm (males) or eggs (females) during this time.

Birth Control Specifications: If you can become pregnant or father a child, you must use a barrier method (such as a male latex condom [with or without spermicide]) and

a highly effective birth control method. Talk with the study doctor about what birth control methods you should use during this study.

Highly effective birth control methods include:

- Combined (estrogen- and progestin-containing) hormonal birth control pills, intravaginal methods (such as vaginal rings), or patches that stop ovulation
- Progestin-only hormonal birth control pills, injections, or implants that stop ovulation
- Intrauterine device (IUD)
- Intrauterine hormone-release system (IUS)
- Bilateral tubal occlusion ("tubes tied")
- Vasectomy or vasectomized partner

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

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your immediate removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson 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.

If you become injured or ill as a direct result of taking part in this study, the sponsor may pay for the treatment of the injury or illness. MD Anderson cannot determine at this time what you may be reimbursed for. A financial counselor will be made available to you after the injury or illness is reported.

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. Alessandra Ferrajoli, at (713) 792-2063) any questions you have about this study (such as questions about the study procedures or treatments, study-related costs to you or your health plan, reporting an illness, injury, or other problem, leaving the study before it is finished, or expressing a concern about the 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, Loxo Oncology, Inc., the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson. This can happen because:
   - The researcher believes that it is not in your best interest to stay in the study.
   - You become ineligible to participate.
   - Your condition changes, and you need treatment that is not allowed while you are taking part in the study.
   - You do not follow instructions from your study doctors.
   - The study is suspended or canceled.

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.

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

9. This study is supported by: Loxo Oncology, Inc.

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 Loxo Oncology, Inc. and/or shared with other researchers and/or institutions for use in future research. This is a required part of this study.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. 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 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 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.

Genetic Research

Research samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA).

This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

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

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

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

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Loxo Oncology Inc., who is a supporter of this study, and/or any future supporters of the study
   - Representatives of Loxo Oncology, Inc. (such as the CRO, IQVIA)
   - Government agencies in other countries
   - 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 study could be published in an article or presented at medical

meetings but would not identify you by name.

You will not be personally identified (for example, mentioned by name) in any reports or publications that may result from this research study

You may change your mind and withdraw this Authorization at any time.

You will be given a signed and dated copy of this form to keep.

You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this consent form you agree that you might not be able to review or receive your records related to the study until after the study has been completed.

Your medical files may be reviewed at the hospital (or study doctor's office) or remotely (outside of the study center) to check the information and verify the clinical study procedures, without breaking your confidentiality. If your medical files are reviewed remotely, the records will include your study subject number but will not include your name or other directly identifiable information, unless these records will be reviewed directly through the study center's secure electronic medical records portal or through other secure viewing platform where permitted by local regulations and regulatory authority guidance.

Whether your medical files are reviewed at the study center or remotely for the purposes of the study, your records will be kept secure during this process.

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.)