THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase 2 Basket Study of BXCL701, a Small Molecule Inhibitor of Dipeptidyl Peptidases (DPP), Administered in Combination with Pembrolizumab in Patients with Advanced Solid Cancers
2019-0748

Subtitle: BXCL701- Protocol V.10 – ICD Version 15 July 2021

Study Chair: Aung Naing

_____ _____
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).

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

STUDY SUMMARY

The goal of this clinical research study is to learn if BXCL701 in combination with pembrolizumab (Keytruda®) can help to control advanced solid cancers.

This is an investigational study. BXCL701 is not FDA approved or commercially available. It is currently being used for research purposes only. Pembrolizumab is FDA approved and commercially available for the treatment of many different types of cancers, but may not be approved for your type of cancer. It is considered investigational to give BXCL701 and pembrolizumab in combination to treat advanced solid tumors.

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

Taking 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 may not want to take part in this study due to the need for hospitalization.

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

BXCL701 will be provided during the study at no cost to you. You and/or your insurance provider will be responsible for the costs of pembrolizumab.

You may receive BXCL701 and pembrolizumab for as long as the study doctor thinks it is in your best interest.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive 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. You will have screening tests to help the doctor decide if you are eligible. The following tests and procedures will be performed within 4 weeks before you can begin receiving the study drug:

- You will have a physical exam.
- Urine and blood (about 5 tablespoons) will be collected for routine tests. This blood draw will include a pregnancy test, if you can become pregnant. To take part in this study, you must not be pregnant.
- You will have either a CT scan or an MRI to check the status of the disease.
- If you have had a tumor biopsy or cancer surgery in the past and leftover tumor tissue is available, it may be collected for biomarker testing.
- You will also have a tumor biopsy collected for biomarker testing.

You should tell your study doctor about any drugs you take while you are in this study, including prescription and over-the-counter medications, vitamins, herbal remedies, and supplements.

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 42 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

Each cycle is 21 days.

You will take BXCL701 tablets by mouth on Days 1-14 of each cycle. Do not take BXCL701 during Days 15-21. Your study doctor or study coordinator will give you specific instructions on how many tablets to take. You should take your study medication in the morning and in the evening at the same times of day every day. BXCL701 should not be taken on an empty stomach.

You will be given a diary card to write down when you take each dose of BXCL701. You will need to bring the diary card and bottle(s) containing study drug (even if the bottle is empty) with you to each clinic visit.

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

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.

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.

You may be asked to drink at least 8 cups (2 liters) of liquid a day while on treatment. This is to help you stay hydrated and maintain your blood pressure. You may be asked to drink liquids that contain potassium, chloride, and magnesium, such as sports drinks. You may need to drink more if you are doing strenuous activities that increase your heart rate or make you sweat. Your doctor may decide to give you fluids by vein in the clinic on Day 1 of Cycle 1. This may be repeated more often, if the doctor thinks it is needed.

Follow the study doctor’s instructions about maintaining/increasing fluid intake

Study Visits

At **every clinic visit**, you will have your vital signs measured, including temperature, heart rate, breathing rate, and blood pressure. At some visits, your height and/or weight will be measured as well.

During Cycle 1, you will also need to measure your blood pressure at home and right down the results 2 times a day (in the morning and afternoon/evening, before each dose). You will be given a blood pressure log (diary) to fill out with these at-home measurements. The study team will show you how to take your blood pressure at home. If you do not have a blood pressure cuff at home, one will be provided to you to use while on study. You should not take your dose of BXCL701 until after you have measured your blood pressure. If your systolic (upper number) pressure is below 100 mmHg, do not take your dose of BXCL701. Instead, call your study doctor right away. The study team will call you regularly during the first 2 weeks of Cycle 1 to ask about your blood pressure measurements. You will be asked to bring the blood pressure log with you to every clinic visit.

On **Day 1 of Cycle 1**:

- You will have a physical exam.
- Blood (about 7 tablespoons total) will be drawn for immune system, biomarker, and/or routine testing before the BXCL701 dose and 2 times during the 24 hours after the dose. Part of this blood sample will be banked (stored) at MD Anderson for immune system testing in the future.
- 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 **Day 2 of Cycle 1:**

- You will have physical exam
- Blood (about 3 tablespoons total) will be drawn for immune system, biomarker, and/or routine testing before the BXCL701 dose. Part of these blood samples will be stored at MD Anderson for immune system testing in the future.

On **Day 4-5 (-1 day) of Cycle 1:**

- You will have a physical exam.
- Blood (about 1½ tablespoons total) will be drawn for routine tests.

On **Days 8 and 15 of Cycle 1:**

- You will have a physical exam.
- Blood (about 5-7 tablespoons, depending on the day) will be drawn for immune system, biomarker, and/or routine testing before the BXCL701 dose.

On Day 14 of Cycle 1:

- Blood (about 1½ tablespoons total) will be drawn for immune system testing before the BXCL701 dose. Parts of this blood sample will be stored at MD Anderson for immune system testing in the future.

On Day 1 of Cycle 2:

- You will have a physical exam.
- Urine will be collected for routine testing.
- Blood (about 7 tablespoons total) will be drawn for immune system, biomarker, and/or routine testing before the BXCL701 dose and 2 times during the 24 hours after the dose. Part of this blood sample will be stored at MD Anderson for immune system testing in the future.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test.

On **Days 2 of Cycle 2:**

- Blood (about 1½ tablespoons total) will be drawn for immune system testing before the BXCL701 dose. Parts of this blood sample will be stored at MD Anderson for immune system testing in the future.

On **Days 8 and 15 of Cycle 2:**

- You will have a physical exam.
- Blood (about 5-7 tablespoons, depending on the day) will be drawn for immune system, biomarker, and/or routine testing.
- Between Day 8 and Day 14 of Cycle 2, you will have a tumor biopsy collected for biomarker testing.

On Day 1 of Cycles 3 and beyond:

- You will have a physical exam.
- Blood (about 7 tablespoons total) will be drawn for biomarker and/or routine testing before the BXCL701 dose.
- Urine will be collected for routine testing.
- If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test.

On **Day 1 of Cycle 4 and then every 9 weeks after that**, you will have either a CT scan or an MRI to check the status of the disease. If the study doctor thinks it is needed, you may have a CT scan or MRI every 6 weeks instead of every 9 weeks.

On **Day 8 and 15 of Cycles 3 and Cycle 4,** blood (about 5 tablespoons total) will be drawn for routine testing before the BXCL701 dose.

End of Study Visit

Within 21 days after you stop receiving the BXCL701 and pembrolizumab:

- You will have a physical exam.
- Blood (about 4 tablespoons) will be drawn for routine tests.
- You will have either a CT scan or MRI and bone scan to check the status of the disease.

Follow Up Visit

About 30 days after your last dose of BXCL701:

- You will be asked about any side effects or any medication changes.
- If the disease got worse, you will be asked about your health every 90 days by phone. The phone call be about 10 minutes long.

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.

BXCL701 and pembrolizumab may 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.

BXCL701 Side Effects

This is an early study of BXCL701, so the side effects are not well known. Based on studies in animals and early testing in humans, BXCL701 may cause the following side effects:

• fluid around the heart • swelling • low blood pressure (possible dizziness and/or fainting) • shock due to low blood pressure • blood clots in a vein (possible pain, swelling, and/or redness) • dizziness • dehydration/ and/or bleeding • abnormal blood acid/base balance (possible organ damage)fever • migraine • fatigue • difficulty sleeping • skin rash	• shivering • sweating • flushing • fainting • paleness • hair loss (partial or total) • low blood sugar • nausea/vomiting • diarrhea • constipation • sore throat • hoarseness • taste changes • weight gain/weight loss • nosebleed • blood in the stool • low platelet cell count • breakdown of muscle tissue (possible kidney failure)	• abnormal kidney test (possible kidney damage) • muscle pain • eye inflammation • blurred vision • low oxygen level in the blood (possible lightheadedness and/or blue colored skin) • difficulty breathing • lung inflammation (possible difficulty breathing) • cough • infection, possibly severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

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

Occasional (occurring in 3-20% of patients)

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

Frequency Unknown

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

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

• low blood pressure (possible dizziness/fainting) • heart inflammation • build-up of fluid in the tissue around the heart	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress	• kidney failure • build-up of fluid around the lungs • immune response that causes the body to

• blood vessel inflammation (possible bleeding and/or bruising) • seizure • immune system damage to the nervous system (causing muscle weakness, numbness, and/or paralysis) • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract)	• pituitary gland inflammation (possible headaches) • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis) • inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure)	attack itself (possible organ damage) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • immune system reaction (possible fever, jaundice, liver/spleen enlargement, irritability, and/or seizures) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)

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

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

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, which may create a need for blood transfusions.

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.

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.

A **standard bone scan** exposes you only to the radiation that comes from injecting the standard radioactive imaging solution for bone imaging.

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 2 forms of birth control during the study and for at least 4 months (females) or 60 days (males) after your last dose of study drugs, if you are sexually active.

Birth Control Specifications: If you can become pregnant, you must use 2 forms of birth control while you are on study. Acceptable forms of birth control include

intrauterine device (IUD), hormonal birth control methods, and surgical sterilization in a combination with a barrier method (such as condoms).

If you are male, you must use barrier birth control (such as a condom with spermicidal foam/gel/film/cream/suppository). If your partner can become pregnant, they must also use one of the above birth control methods.

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

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

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a tumor biopsy performed at the End of Treatment visit. Some participants who agree to these optional procedures may have biopsies at only some of those time points. The study team will let you know how many biopsies you may have if you agree.

Researchers will use these samples for tests to help learn about how your body is responding to the study drug. The type of biopsy performed and the timing of the collection will depend on how easily and safely an available sample can be collected, and if there is any inflammation.

You will not be compensated for any patents or discoveries that are produced by this research.

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 procedures 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 the End of Treatment 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, BioXcel Therapeutics Inc. 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. Aung Naing, 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. If you withdraw from this study, you can still choose to be treated at MD Anderson. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your

medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, BioXcel Therapeutics, Inc., 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, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

9. This study is supported by: BioXcel Therapeutics, 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 BioXcel Therapeutics, Inc. 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.

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.

Genetic Research
Research samples collected from you as part of this study may 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.

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
   - BioXcel Therapeutics, Inc. who is a supporter of this study, and/or any future sponsors 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.

You will not be identified in any presentation or publication of the results of this study. The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed

The sponsor 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 (magnetic resonance imaging) 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
(Adult Participants Only)

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 Protocol 2019-0748.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
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

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE

_____
PRINTED NAME OF PARENT/GUARDIAN

_____ _____
SIGNATURE OF PARENT/GUARDIAN DATE
Signature of Other Parent (Optional, unless required by the IRB.)

_____
PRINTED NAME OF PARENT/GUARDIAN

____The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____Other parent is deceased, unknown, incompetent, or not reasonably available.

____Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

__**X**__ The IRB has determined that the signature of both parents is NOT required.

WITNESS TO PARENTAL/GUARDIAN PERMISSION
I was present during the explanation of the research to be performed under Protocol 2019-0748. The child participant was also present. In my opinion, the parent(s)/guardian provided permission for the child to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE PARENTAL/GUARDIAN PERMISSION

ASSENT OF MINOR
(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR (Age 13-17) DATE

_____
PRINTED NAME OF MINOR

WITNESS TO ASSENT

I was present during the explanation of the research to be performed under Protocol 2019-0748. The child participant was also present. In my opinion, the child assented to participate in the research. (Note: If obtaining assent, a witness signature is required.)

_____ _____
SIGNATURE OF WITNESS TO THE ASSENT (OTHER THAN PARENT/GUARDIAN OR MEMBER OF THE STUDY TEAM) DATE

_____
PRINTED NAME OF WITNESS TO THE ASSENT

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 below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION