Informed Consent/Authorization for Participation in Research

Title of Research Study: A Phase II Study of Perioperative Paclitaxel in Patients with Gastric Adenocarcinoma and Carcinomatosis or Positive Cytology

Study Number: 2023-0331

Principal Investigator: Brian Badgwell

_____ _____
Participant's Name Medical Record Number

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you have gastric cancer (stomach cancer).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this clinical research study is to learn about the effects of paclitaxel and gastrectomy (surgery to remove all or part of the stomach) on improving outcomes in patients with gastric cancer.

This is an investigational study. Paclitaxel is FDA approved and commercially available for the treatment of gastric cancer. Its use in this study is considered investigational because it is given within the abdomen. Gastrectomy is performed according to standard surgical principles.

The study doctor can explain how the study therapy is designed to work.

How long will the research last and what will I need to do?

You are expected to be in this research study for up to 3 years after you have surgery.

As part of this study, you will receive paclitaxel every 2 weeks for 6 weeks, and then you may have a gastrectomy based on what the doctor thinks is in your best interest. You may then receive additional paclitaxel every 2 weeks for 6 weeks. You will have tests and procedures (such as blood draws and imaging scans) for routine tests and to check the status of the disease.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

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 life-threatening. The most common side effects include a low white blood cell count (which increases your risk of infection), fatigue, nausea, hair loss or thinning, problems with the abdominal chemotherapy catheter, and abdominal pain or discomfort.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

It cannot be promised that there will be any benefits to you or others from your taking part in this research. However, the study therapy may help to control the disease. Future patients may benefit from what is learned.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Instead of being in this research study, you may choose to receive treatment with chemotherapy given by vein according to standard of care. You may choose to receive other investigational therapy, if available. These alternative treatments have risks and benefits that may be the same or different than those in this research study. The study doctor can discuss these alternative treatments, including their risks and benefits, with you.

You may choose not to have treatment for cancer at all. If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually, this care can be provided at home. If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study chair, Dr. Brian Badgwell, at 713-745-7351.

This research has been reviewed and approved by an Institutional Review Board (IRB – an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected about 30 people at MD Anderson will be enrolled in this research study.

What happens if I agree to be in this research?

Screening Tests

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

- You will have a physical exam.
- Blood (about 2-3 tablespoons) will be drawn for routine tests.
- You will have imaging scans (such as an MRI, CT, or PET/CT scan) to check the status of the disease.
- If you can become pregnant, blood (about 2-3 teaspoons) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Pre-Surgery Treatment

If you are found to be eligible to take part in this study, you will receive paclitaxel every 2 weeks for 6 weeks (3 doses total). Paclitaxel is given intraperitoneally (directly into the abdominal cavity). The infusion time will depend on the size of your abdominal cavity, but it will take at least 30-60 minutes.

To receive the drug intraperitoneally, you will have a port placed in your abdominal cavity. You will be given a separate consent form that will describe this procedure and its risks in detail.

During pre-surgery treatment, you will be followed according to standard-of-care procedures. This will include blood draws for routine tests and evaluations for side effects. This will be discussed with you.

If you are receiving immunotherapy or targeted therapy as part of your standard care, you may continue to receive it during this study.

You will also be given standard drugs before each dose of paclitaxel (both pre-surgery and post-surgery) to help decrease the risk of side effects. These standard drugs include dexamethasone, diphenhydramine, and famotidine. You may ask the study staff for information about how the drugs are given.

Pre-Surgery Visit

Prior to your surgery, you will complete standard-of-care procedures, including a CT, MRI or PET/CT scan, blood draws for routine tests, and checks for side effects.

Surgery

At least 3 weeks after completing paclitaxel therapy, you will have a gastrectomy if the study doctor thinks it is in your best interest. The surgery will be performed according to standard of care. You will be given a separate consent form that will describe this procedure and its risks in detail. You will receive post-surgery treatment according to

standard-of-care procedures while you are in the hospital. This will include post-surgery laboratory tests and daily vital sign measurements (such as blood pressure and heart rate).

If you do not have a gastrectomy, such as if the disease gets worse or if you do not want to, your treatment will be evaluated by your doctor. You may continue receiving paclitaxel, have a break from treatment, or change treatment based on what is best for you. You will be followed by the study staff as described in the Follow-Up section below.

Post-Surgery Treatment
You will not receive paclitaxel for at least 3 weeks after your gastrectomy. Then you will receive paclitaxel intraperitoneally every 2 weeks for another 6 weeks. After completing study therapy, the doctor will decide if you will continue receiving paclitaxel, have a break from treatment, or change treatment based on what is best for you.

You will continue to be followed post-surgery according to standard-of-care procedures including blood draws for routine tests and checks for side effects.

Follow-Up
Every 6 months after you complete study treatment, the study staff will check on how you are doing, and you will have imaging scans to check the status of the disease.

Follow-up may be done by phone, and the imaging scans may be done outside of the study site. If you are called, each call will take about 10 minutes.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Tell the study team about any symptoms or side effects you have, follow study directions, and come to all study appointments (or contacting the study team to reschedule).
- Tell the study doctor/study staff about all medications that you are taking or plan to take, including prescription and over-the-counter medications, supplements, vitamins, and herbal remedies.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

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 withdraw from this study, you can still choose to be treated at MD Anderson.

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 then decide if you need to have any visits or tests to check on your health.

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.

Is there any way being in this study could be bad for me? (Detailed 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.

Paclitaxel, diphenhydramine, and famotidine each may 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 infection (such as pneumonia, nail infections, and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Paclitaxel Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • swelling • flushing • hair loss (partial or total)	• nausea/vomiting • diarrhea • low blood cell counts (red/platelets/white) • abnormal liver tests (possible liver damage)	• nerve damage (possible numbness, pain, and/or loss of motor function)

• mouth blisters/sores (possible difficulty swallowing)	• pain (muscle/joint) • weakness	• abnormal kidney test (possible kidney damage) • wheezing/shortness of breath • allergic reaction • infection

Occasional (occurring in 3-20% of patients)

• low blood pressure (possible dizziness/ fainting) • slow heartbeat • fever • blood clots in a vein (possible pain, swelling, and/or redness)	• skin rash • abdominal pain • abnormal liver tests (possible yellowing of the skin and/or eyes)	• lung damage (possible shortness of breath) • injection site reaction (possible redness, swelling, skin discoloration)

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

• fast/irregular heartbeat • heart failure • heart attack • decreased blood supply to the heart • high blood pressure • fainting • decreased brain function (possible paralysis and/or coma) • decreased brain function due to liver damage • seizure • severe sunburn-like rash at site of previous radiation (called radiation recall) • death of skin • worsening of existing scleroderma (severe hardened skin, which	• inflammation at the site of previous tissue death • very severe blistering skin disease (with ulcers of the skin and digestive tract) • very severe blistering skin disease (loss of large portion of skin) • inflammation of the pancreas (possible abdominal pain) • inflammation of the intestines • dehydration • hole in the intestines (possible leaking contents into the abdomen) • decreased blood flow to part of the bowel (possibly causing death of tissue)	• intestinal blockage • difficulty walking • liver damage and/or failure • hearing loss • decreased kidney function • blockage in the lung (possible pain and/or shortness of breath) • lung inflammation (possible difficulty breathing) • blood clots in the lung (possible failure to breathe) • difficulty breathing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

can cause difficult movement)	• paralysis of the intestines	• tissue death at the injection site caused by drug leakage

Dexamethasone Side Effects

It is not well known how often the following side effects may occur.

• high blood pressure • irregular, fast, and/or slow heartbeat • enlarged heart • heart failure • tearing of the walls of the heart (post-heart attack) • blood vessel inflammation (possible bleeding and/or bruising) • blood clots in a vein (possible pain, swelling, and/or redness) • blood clots in the arteries • swelling (such as tissue and/or abdominal swelling) • dizziness • shock • fainting • headache • increased pressure in the skull or between the skull and brain (possible headache, vision changes, and/or mental status changes) • seizure • depression • fatigue and anxiety • mood swings • personality changes • mental disorders	• decreased ability to process carbohydrates • high blood sugar (possible diabetes) • diabetes • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • abnormal blood acid/base balance (possible organ damage) • low blood levels of potassium (possible weakness and/or muscle cramps) • high blood levels of sodium (possible weakness and/or swelling) • sugar in the urine • body-wide loss of proteins (possible weakness and/or swelling) • build-up of fat in abnormal areas • weight gain • increased appetite • digestive system bleeding • small red or purple spots in the mouth • esophageal sore	• inflammation of nerves (possible pain and/or loss of motor or sensory function) • joint disease (possible pain) • pain or loss of function of the hips or shoulders due to bone death • broken bones • loss of muscle • muscle damage causing weakness • nerve damage (loss of motor or sensory function) • loss of bone strength (possible broken bones) • abnormal sensation (such as pins and needles) • tendon tear • collapse of bones in the spine • enlarged liver • abnormal liver tests (possible liver damage) • bulging eye • increased pressure in the eye (possible vision loss, pain, and/or blurry vision) • cataracts (clouding of the lens of the eye) • hiccups

• euphoria (unusual feelings of happiness or well-being) • difficulty sleeping • fatigue/lack of energy • darkening and/or lightening of the skin • tiny dots on the skin • impaired wound healing • skin rash, redness, and/or dryness • fragile and/or thinning skin • skin test reaction impaired (due to a lowered immune system) • stretch marks • hives • acne-like rash • hair loss (partial or total) • hair growth • sweating • tissue death • Cushing's syndrome (possible weakness, diabetes, and/or bone weakness)	• hole in the intestines (possibly leaking contents into the abdomen) • nausea • itching near the anus • inflammation of the pancreas (possible abdominal pain) • stomach ulcer • changes to the menstrual cycle • problems with production of sperm • bruising • muscle weakness	• fluid in the lung (possible difficulty breathing) • breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage) • infection • allergic reaction (such as skin reaction) • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Dexamethasone may cause you to develop another type of cancer.

Dexamethasone may cause a false-positive or false-negative skin test (such as a test for tuberculosis [TB]). If you need to have a skin test performed, tell the doctor that you are taking dexamethasone.

Stopping dexamethasone suddenly may cause withdrawal symptoms (such as fever, muscle/joint pain, and fatigue). This is because dexamethasone affects your adrenal glands and may cause your body's hormone levels to change. The study doctor will help you stop dexamethasone safely, if you want to stop taking the study drug. Do not just stop taking dexamethasone.

Diphenhydramine Side Effects

It is not well known how often the side effects of diphenhydramine may occur.

• chest tightness • extra heartbeats • low blood pressure (possible dizziness/ fainting) • irregular/fast heartbeat • chills • confusion • seizures • loss of coordination • dizziness • headache • euphoria (unusual feelings of happiness or well-being) • unusual excitement • irritability • nervousness • restlessness • sedation • fatigue or sleepiness	• difficulty sleeping • sweating • loss of appetite • constipation • diarrhea • dry mucous membranes • abdominal pain • nausea • throat tightness • vomiting • dry mouth • changes to the menstrual cycle • difficult and/or frequent urination • inability to urinate • low blood cells (white and platelet) • anemia due to destruction of red blood cells • tremor	• abnormal sensation (such as pins and needles) • inflammation of nerves (possible pain and/or loss of motor or sensory function) • blurry and/or double vision • inflammation of part of the ear that controls balance • ringing in the ears • stuffy nose • increased thickness of secretions in the lung • wheezing • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

Famotidine Side Effects

Common (occurring in more than 20% of patients)

• none known at this time

Occasional (occurring in 3-20% of patients)

• agitation	• headache	• vomiting

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

• irregular heartbeat • swelling (face and/or tissue) • fever • seizure	• diarrhea • low blood cell counts (red, white, platelets) • blockage of the bile tract (possible body yellowing and/or abdominal pain)	• breakdown of muscle tissue (possible kidney failure) • difficulty breathing due to narrowing of the airways

• hallucinations (seeing or hearing things that are not there) • dizziness • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract)	• liver damage • abnormal sensation (such as pins and needles)	• lung inflammation (possible difficulty breathing) • infection • life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)

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.

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.

A PET scan may cause you to 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 technicians will give comfort, or the scanning will be stopped. The PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

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.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

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 during the study if you are sexually active.

Birth Control Requirements: If you can become pregnant or father a child and you are sexually active, you must use birth control during the study and for 3 months after your last dose of study drug:

- If you can become pregnant, acceptable methods of birth control include birth control pills, implants, or injections or a double barrier method.
- If you can father a child, you must use a double barrier method (condom with diaphragm).

Talk to the study doctor about the birth control methods you should use.

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.

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

Will it cost anything to be in this study? Will I be paid to be in this study?

You and/or your insurance provider will be responsible for the cost of paclitaxel.

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.

Taking part in this study may result in added costs to you (such as transportation, parking, meals, or unpaid leave from work). You may have to pay for medication prescribed to treat or prevent side effects, and you may have to visit the clinic/hospital more often than if you were not participating in this study.

If you have insurance, talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this study. Also, find out if you need approval from your plan before you can take part in the study.

You may ask that a financial counselor be made available to you to talk about the costs of this study.

You will not receive any compensation for taking part in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

The sponsor, monitors, auditors, the IRB, and the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

The results of this research may be published in scientific journals or presented at medical meetings. However, your identity will not be disclosed. Your name and other identifying information will be kept confidential.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data or samples be used for 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 shared with other researchers and/or institutions for use in future research.

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

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)

- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
- call the study doctor (Dr. Brian Badgwell, at 713-745-7351) or 713-792-2121 (24 hours)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson 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.

What else do I need to know?

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

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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

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
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

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 do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by federal law.

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.)