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Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study in people with metastatic adenocarcinoma of the gastric or gastroesophageal junction of two unapproved drugs called pembrolizumab and epacadostat. This document is to be used as a guide for a discussion between you and your study doctor and the study team. This form, called an informed consent document, is designed to help you understand why this study is being done, what parts of the study is "research" or "experimental," what will be asked of you if you choose to participate; possible risks; any inconveniences or discomforts you may experience; and other important information. This form may also be helpful as a reference if you choose to participate, as a reminder of what your role in the study is, and who to contact if you have questions at any time during your participation. You are urged to discuss any and all questions you have about this study with members of the study team. If you wish, you can also discuss this study and your role with your family doctor or medical provider.

The purpose of this study is to determine the effects, good and/or bad, of the drugs pembrolizumab and epacadostat to find out if the combination helps treat cancer, and is safe for people with cancer to take. You were selected as a possible participant in this study because you have been diagnosed with metastatic gastroesophageal junction or gastric adenocarcinoma.

The use of pembrolizumab and epacadostat in this research study is investigational. The word "investigational" means this treatment is not approved to sell in the United States by the Food and Drug Administration (FDA). However, the FDA is allowing the use of these drugs in combination in this study.

If you decide to terminate your participation in this study, you should notify George A. Fisher, Jr., M.D., PhD at [redacted] or a member of the research team.

This is a single-institution study, so it will only take place at Stanford University and Stanford University expects to enroll a total of 30 people with metastatic gastroesophageal junction or gastric adenocarcinoma. This study is looking to enroll approximately 15 research study participants per year.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

You will be told of the results of tests that are part of your standard clinical care, but you may not be told the results of certain research tests, including any future research tests.

DURATION OF STUDY INVOLVEMENT

It is unknown exactly how long you will stay on the study. The epacadostat treatment is given daily by mouth throughout each cycle. The pembrolizumab infusion will be given as an IV infusion every three weeks. Your treatment in this study will continue unless one of the following occurs:

- You withdraw your agreement to continue to take part in this research study;
- Your cancer becomes worse;
- You need a treatment that is not allowed by the study protocol;
- You or your doctor decides that the side effects are too severe;
- You are a woman and have become pregnant;
- The study is terminated; or
- You are removed from the research study for any of the following reasons:
    - You do not follow the study team's instructions for the study.
    - Other appropriate and/or administrative reasons as determined by your doctor

When your participation in this study ends, you may be asked to return for a final visit to have some end-of-study evaluations or tests. You will have your tumor size measured by MRI or CT scan every 9 weeks after the first study drug dose for up to 18 months and then every 12 weeks. The study staff will contact you during those visits to see how your cancer is doing. These contacts may occur during your routine visits to your doctor or by telephone calls. You are also free to stop participating at any time you decide to do so.

ABOUT THE STUDY DRUGS

All participants in this study will receive both pembrolizumab and epacadostat.

Pembrolizumab was FDA-approved in September 2017 for locally advanced or metastatic, gastric or gastroesophageal junction adenocarcinoma whose tumors

express PD-L1 as determined by an FDA-approved test. Patients must have had disease progression on or after two or more prior systemic therapies. Pembrolizumab is considered investigational in the first and second line settings and for PD-L1 positive patients.
Pembrolizumab was approved by the FDA in September 2014 as "Keytruda" to treat "advanced melanoma" after failure of certain other treatments. As of September 2017 Pembrolizumab was approved by the FDA to treat: Non-Small Cell Lung Cancer, Head and Neck Squamous Cell Carcinoma, classic Hodgkin Lymphoma, Urothelial Cancer, and Microsatelite instability – High solid tumors (MSI-H).

Pembrolizumab is an antibody that will be administered by intravenous (IV) infusion. Antibodies are proteins that the immune system uses to fight infection. Pembrolizumab has been designed to block PD-1. Your body normally makes PD-1, and it can stop or slow your body's immune response to infection or a cancer. An antibody to PD-1 may stop it from turning off your body's immune response to cancer, and may therefore help your body's immune system fight the cancer.

Epacadostat is not approved by the FDA for treatments of your type of cancer at this time and is therefore considered "investigational" or "experimental". This experimental drug epacadostat is an oral medication that blocks an enzyme called IDO. Doctors think that tumors use IDO to escape attack by your body's immune system, so by blocking this IDO enzyme it may help your body attack the tumor cells more effectively.

PROCEDURES

If you choose to participate, the Protocol Director and his research study staff will describe all procedures to be followed.

It may be harmful to enter this study while receiving some medications; therefore, you may need to stop taking some medications. Your study doctor will review your medications and provide you with specific instructions.

Before you join this study, the Protocol Director and/or the research study staff will review this document with you, and ask you to sign this informed consent document. After you have signed this document, and received a signed copy, the study will begin with a screening visit.

Screening

The screening period is held within 28 days before starting the study treatment to find out if you can be in the study. During this period, you will need to come to the clinic or study site for multiple tests. More than one screening visit may be required.

If these tests show that you can be in the study and you choose to take part, then you will be entered in the study. The following screening examinations, tests, or procedures will be performed after you have given consent to participate in this study:

- **Medical history**, including information about you and your cancer, previous treatments for your cancer and other medications you are taking or have taken. Certain medications are not allowed to be taken during the study treatment.
- In addition, you will be asked if you have ever had a condition called serotonin syndrome. Serotonin syndrome is something that can happen when there is an increase in the level of a protein called serotonin in your blood. This can happen when certain drugs are combined. The symptoms you may have had if you had serotonin syndrome include: tremor, overactive reflexes, spontaneous ocular (eye) or inducible twitching together with agitation, fevers, sweating or muscle stiffness
- Complete **physical exam** including vital signs (heart rate, temperature, breathing rate, blood pressure, height and weight)
- **EKG** test (or ECG, Electrocardiogram) to test the heart's electrical activity.
- **Performance Status** (questions about your ability to perform everyday activities)
- Your tumor size will be measured by **CT scans** or **MRI**.
- Standard **blood and urine tests**, using up to 6 teaspoons of blood (30 mL), to measure your organ function, white blood cells, red blood cells and platelets, your blood sugar and blood electrolytes, and endocrine function and if you are female and able to become pregnant, to confirm you are not pregnant. You will not be allowed to enter the study if you are pregnant or lactating.
- You need to undergo a **tissue biopsy**, if your doctor determines your tumor is easy and safe to access to get a sample. This means tissue samples of your cancer will be collected for analysis. The tissue sample needs to be provided before you can receive any treatment and once while you are on treatment. Research using tissues, such as from your tumor, is an important way to try to understand human disease. The biopsy may be obtained with a hollow needle or a special cutting instrument.

Handling of Blood and Tissue Samples

Your samples may be sent outside of Stanford for analysis. Donors of samples do not retain any property rights to the samples.

On-Study Procedures

Research blood will be taken to monitor how the drug, throughout the study, will affect your body. These tests require approximately 40 mL (8 teaspoons) of blood taken prior to each infusion of pembrolizumab.

TREATMENT REGIMEN

All subjects participating in this study will be enrolled to receive both epacadostat and pembrolizumab at a single dose level. Your dose will not increase and your schedule (how often you receive treatment) will stay the same during your treatment period with the study drugs.

If you continue to be eligible for study participation after screening, you will begin epacadostat (study drug) twice daily. Epacadostat comes in 100mg capsules.

Epacadostat capsules should be taken orally twice daily, about 12 hours apart. You must swallow the capsules whole with a full 8-ounce glass of water and not chew them. It is very important that you follow these instructions listed above because they could change the safety and how well the study drug works.

Bottles containing epacadostat capsules will be given to you periodically. It is very important that you take this medicine just as the doctor tells you. Do not miss any capsules. You will be given enough epacadostat pills to last until your next visit, a diary card so that you can record the date, time and number of pills you take each day and a reminder card with details about your next visit. It is important to tell the study staff about any other medications you are taking during the study, including prescription drugs, over-the-counter medicines and vitamins. You must bring your epacadostat bottle(s) back to the clinic at regular intervals so the study staff can make sure you are taking your epacadostat, as you should. The study staff will review the pill count with you to ensure accuracy and assess compliance.

If you stop taking the study drug at any time, you must tell your study doctor immediately. When you return to the clinic for your next visit, you must return all empty bottles and remaining epacadostat as well as your study diary. The study team will review everything to make sure you are taking the drug appropriately and completing this diary as requested.

You will also be given an information sheet on serotonin syndrome (described above under screening) that includes the signs and symptoms to look for on your first day of treatment. If you experience any of the symptoms noted on the information sheet you should seek immediate medical attention. This syndrome has not been seen in patients treated with epacadostat. If it were to occur, it would be expected to occur right away on your first day of dosing, usually within 6 hours.

Pembrolizumab will be administered by intravenous (IV) infusion. This process involves inserting a needle into a vein in your arm. You will receive this agent by vein every 3 weeks. This three-week period is called a cycle. The number of cycles you receive will depend on your disease status, your overall condition, and whether you choose to continue in the study.

If you have any side effects during the treatment period, you and your doctor will decide if you should continue in the study.

You will return to your doctor's office at regular intervals so that your disease can be monitored and routine blood tests and safety evaluations can be carried out. Please tell your study doctor or study staff if you have any unusual symptoms. You will be closely monitored for any side effects and you should report any changes in the way you feel to your study doctor. If you experience any side effects, your study doctor may instruct you to stop the study drug temporarily and restart after the side effect has resolved.

You will continue receiving combination study treatment in continuous 21-day cycles for up to 24 months, and have not had disease progression or met any criteria for study withdrawal.

If you stop treatment with stable disease or better, you may be eligible for up to one year of additional therapy if you progress after stopping study treatment. This retreatment is termed the Second Course Phase of this study and is only available if the study remains open and you meet several conditions.

If you restart treatment you will be retreated at the same dose and dose interval as when you last received treatment. Treatment will be administered for up to one additional year.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Take the study drug as instructed.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.

- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep the study drug in a safe place, away from children and for your use only.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. George A. Fisher, Jr at (650) 498-6000. We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.

The Protocol Director may also withdraw you from the study and the study medication may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- We find out it is not safe for you to stay in the study. For example, your health may worsen or we may find that the experimental drug might harm you.
- You are not taking your medication properly or are not coming for your study visits as scheduled
- The doctor feels it is not in your best interest to continue.
- If the sponsor or investigator stops the study or your participation for any reason.
- If your disease progresses
- Unacceptable side effects. You may be removed from the study for any complication of treatment that the investigator feels is life threatening
  - If you do not meet eligibility criteria
  - You need treatment not allowed in the study.
  - The study is cancelled.
  - Other administrative reasons.
  - Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

You must tell your physician and/or the research study staff about all side effects that you have. If you are not honest about side effects, it may not be safe for you to stay on the study. Your doctor may give you medications to help lessen some of the side effects, if needed. All patients on the study will be monitored for side effects.

Potential Side Effects of EPACADOSTAT

Very common risks or discomforts seen in ≥ 10% of patients treated with Epacadostat include the following:

- Fatigue (tiredness)
- Nausea
- Decreased appetite
- Vomiting
- Constipation
- Abdominal (stomach) pain
- Diarrhea
- Joint pain (Arthralgia)
- Back pain
- Fever
- Shortness of breath/difficulty breathing with increased activity
- Cough
- Asthenia (physical weakness)
- Itching
- Headache
- Anemia (low hemoglobin level in the blood), which may cause fatigue
- Pneumonitis
- Rash (includes different types of rash such as itchy rash or rash all over the body or rash that looks like a flat, red area on the skin that is covered with small merging bumps)
- Increased levels of liver enzymes in the blood, possibly due to liver injury caused by the study drugs

Common or potentially serious risks or discomforts seen in >1-<10% of patients treated with Epacadostat include the following:

- Dehydration

- Weight loss
- Dizziness
- Decrease in sense of taste
- Abdominal (stomach) distention
- Upper respiratory infection
- Insomnia
- Chills
- Rapid and/or irregular heart beat
- Stomatitis (inflammation of the mouth and lips)
- Mucosal inflammation (swelling or irritation of the mucous membranes)
- Peripheral edema (swelling in limbs)
- High blood sugar level, which may cause symptoms such as blurry vision, difficulty concentrating, frequent urination, headaches, increased tiredness
- High levels of potassium in the blood, which may cause symptoms such as tiredness, weakness, feeling of numbness or tingling, nausea or vomiting, problems breathing, chest pain or palpitations
- Low levels of sodium in the blood, which may cause symptoms such as mental changes, headache, nausea and vomiting, tiredness, muscle spasms
- Lymphocyte count decrease
- Syncope (fainting)
- Muscle pain
- Hypoxia (low levels of oxygen in the blood or body)
- Hypotension (low blood pressure)
- Nervous system disorders (symptoms of brain edema)
- Dry mouth
- Aseptic meningitis (causes the tissues covering the brain and spinal cord to become inflamed)
- Intestinal obstruction (blockage in the intestines)
- Increased levels of lipase and/or amylase in the blood (enzyme that break down fats and sugars in foods)
- Pneumonia (infection in the lungs), including aspiration pneumonia
- Allergic reaction
- Erythema multiforme (rash that may be a recurrent rash and may have mucosal involvement)
- Hypertension (high blood pressure)
- Urinary tract infection
- Blood creatinine increased (which may indicate the kidney is not functioning normal)
- Pain, including pain in extremities
- Pneumonitis (which may cause symptoms such as dry cough or shortness of breath)

- Hypothyroidism- (underactive thyroid), which may cause symptoms such as tiredness, increased sensitivity to cold, constipation, dry skin, weight gain, puffy face
- Adrenal Insufficiency- which may cause symptoms such as extreme tiredness, weight loss, decreased appetite, darkening of skin, low blood pressure or even fainting, salt craving, low blood sugar
- Sepsis (serious infection; common symptoms include fever, increased heart rate, increased breathing rate, confusion)

Since epacadostat acts on the immune system you may also be at risk for some immune-related side effects. These potential immune-related side effects are listed below:

- Inflammation, sometimes severe, of the digestive system, including the intestines
- Inflammation of the liver
- Inflammation of the skin, including rash and ulcers
- Inflammation of the nervous system, including weakness, numbness and loss of sensation
- Malfunction of important glands, such as the thyroid, pituitary and adrenal glands
- Inflammation of the walls of the lungs, which can be associated with cough, chest pain, or shortness of breath

Although it has not been seen in any human participants to date, epacadostat, when given with certain types of other medications, could possibly cause a condition called serotonin syndrome. Serotonin is a natural chemical in the blood and body tissue that regulates some of your neurologic functions. Serotonin syndrome occurs when there is too much of this chemical in the body. Serotonin syndrome can cause mild, moderate, severe or even fatal effects. As of 29 October 2017, 2 patients in epacadostat clinical trials have had events reported as serotonin syndrome or symptoms of serotonin syndrome. These episodes were mild in severity and resolved with dose interruption. Neither report was clinically substantiated to represent a true case of serotonin syndrome by the study sponsor. Both patients were able to continue treatment with epacadostat. Your study doctor will be monitoring you for signs of serotonin syndrome. Your doctor will also ensure that you are not taking any of the medications that could potentially, cause serotonin syndrome if taken along with epacadostat. It is important that you tell the study team about all the medications that you are taking (including supplements). You will be given an information sheet on serotonin syndrome on study visit 2 that includes the signs and symptoms to look for on your first day of treatment. If you experience any of the symptoms on the information sheet, you should seek immediate medical attention.

Potential Side Effects of PEMBROLIZUMAB (KEYTRUDA®)

Pembrolizumab is also known as KEYTRUDA (approved in USA and several other countries) and is available by prescription to treat a type of skin cancer called malignant melanoma.

Pembrolizumab/KEYTRUDA is being studied by the Sponsor to see if it is effective in treating more than 30 types of cancer and to see what side effects are associated with its use.

As of 30-March-2017, pembrolizumab/KEYTRUDA had been given to about 20,770 patients with various cancers in clinical trials. Men and women with cancer were treated, some for up to approximately 1.5 years. Safety was studied across several cancers treated with different doses: 2 mg/kg every 3 weeks, and 10 mg/kg every 2 or 3 weeks. The side effects seen were similar.

Very common side effects seen in > 20% of patients treated with pembrolizumab/KEYTRUDA include the following:

- Feeling tired, lack of energy
- Nausea
- Feeling not hungry
- Constipation
- Vomiting
- Loose or watery stool
- Itching of the skin
- Rash
- Cough
- Dyspnea (short of breath)
- Headache
- Swelling of legs and/or feet
- Difficulty falling asleep
- Dizziness
- Fever
- Joint pain

Common side effects seen in ≥10% to 20% of patients treated with pembrolizumab/KEYTRUDA include the following:

- Weakness
- Back pain
- Rash
- Hair Loss
- Stomach pain

- Sick to your stomach
- Infrequent or hard stools
- Weight loss
- Loss of skin color
- Upper respiratory tract infection
- Urinary tract infection
- Peripheral neuropathy (weakness, numbness and pain in hands and feet)
- Anemia (Decrease in the total amount of red blood cells or hemoglobin that may cause you to feel tired, weakness and shortness of breath)
- Low level of salt in the blood that may cause you to feel tired, confused, headache, muscle cramps or upset stomach
- Increased levels of liver enzymes in the blood, possibly due to liver injury caused by the study drugs
- Blood in urine

Common side effects seen in ≥1% to <10% of patients treated with pembrolizumab/KEYTRUDA® include the following:

- Not enough thyroid hormone so you may feel tired, gain weight, feel cold, have infrequent or hard stools
- Too much thyroid hormone so you may feel anxious, angry, can't sleep, weak, tremble, sweat, tired, have loose and watery stools
- Inflammation of the lungs so you may feel short of breath and cough. Rarely this might lead to death.
- Inflammation of the bowels/gut that may cause pain in your belly with loose or watery stools
- Inflammation of the skin so you may have peeling of the skin, itching, skin redness
- Dizziness or fainting (low blood pressure), flushing, rash, fever, shortness of breath or sick to your stomach at the time of receiving your infusion (IV) or just after, or pain at the site of infusion

Common serious side effects seen in 1% to 4% of patients treated with pembrolizumab/KEYTRUDA include the following:

- Short of breath
- Feeling tired, lack of energy
- Low level of salt in the blood that may cause you to feel tired, confused, headache, muscle cramps or upset stomach
- Stomach pain
- Anemia (Decrease in blood cells that carry oxygen that may cause you to feel tired or short of breath)

- Inflammation of the lungs so you may feel short of breath and cough. Rarely this might lead to death
- Joint pain
- Weakness
- Back pain
- Inflammation of the bowels/gut that can cause stomach pain with loose or watery stools, or stools that are black, tarry, sticky or have blood or mucus
- Feeling not hungry
- Loose or watery stools
- Dehydration
- Sick to your stomach
- Fever
- Vomiting
- Nausea

Immune-mediated serious side effects seen in 1.0% of patients treated with pembrolizumab/KEYTRUDA include the following:

- Inflammation of the skin so you may have widespread peeling of the skin, itching, and skin redness. More severe skin reactions may involve the inside of your mouth, the surface of your eye and genital areas, and/or may cause the top layer of your skin to peel from all over your body, which can cause severe infection. Rarely these reactions lead to death.
- Inflammation of the liver that may cause a poor appetite, feeling tired, mild fever, muscle or joint aches, upset stomach and vomiting, bleeding and bruising more easily than normal, stomach pain, yellow eyes and skin, and dark urine
- Inflammation of the pituitary gland (a gland in the head), which may cause headaches, upset stomach, changes in behavior, double vision, few to no menstrual cycles, weakness, vomiting and dizziness or fainting.
- Adrenal glands (glands on top of the kidneys) to may not make enough hormone causing tiredness, weight loss, muscle weakness, feeling faint, joint, muscle and abdominal aches, nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan
- Too much thyroid hormone so you may feel anxious, angry, can't sleep, weak, tremble, increased sweating, weight loss, hair loss, tired, have loose and watery stools
- Too little thyroid hormone so you may feel tired, gain weight, feel cold, voice gets deeper, hair loss, have infrequent or hard bowel movements.
- Inflammation of the kidney so you may pass less urine or have cloudy or bloody urine, swelling and low back pain
- Inflammation of the muscles so you may feel weak or pain in the muscles

- Inflammation of the eye so you may have redness of the eye, blurred vision, sensitive to light, have eye pain, see floaters or have headaches
- Inflammation of the pancreas, (a gland in your abdomen that controls sugar levels) so you may have severe upper abdominal pain that may move to the back, sick to your stomach, and vomiting that gets worse when you eat
- Inflammation of the pancreas (diabetes) so you may have too much sugar in your blood, may need to urinate more often, lose weight, feel thirsty, and are likely to need regular insulin shots
- Inflammation of the nerves that may cause pain, weakness or tingling in the hands and feet, and may spread to the legs, arms and upper body leading to severe muscle weakness and possible temporary paralysis
- Inflammation of the middle layer of your heart wall (myocarditis) that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting. Sometimes this condition can lead to death
- Low count of neutrophils, a type of white blood cells
- Low levels of lymphocytes, a type of white blood cells
- Deficiency of platelets in the blood. This causes bruising, and slow blood clotting after injury.
- Increase in the number of eosinophils in the blood, can occur in response to some allergens, drugs, and parasites.

Additional serious side effects seen in <1.0% of patients treated with pembrolizumab/KEYTRUDA® include the following:

- Dizziness or fainting (low blood pressure), flushing, rash, fever, shortness of breath or sick to your stomach at the time of receiving your infusion (IV) or just after, or pain at the site of infusion
- Sarcoidosis - an inflammatory disease marked by the formation of granulomas (small nodules of immune cells) in the lungs, lymph nodes, and other organs
- Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrosis (TEN) – are a type of severe skin reaction that can also involve mucous membranes. It causes skin to blister and peel off
- Encephalitis – inflammation of the brain
- Inflammation of thyroid

In addition to the above, the following side effect(s) have been seen in patients on pembrolizumab, but are still being evaluated to determine if they are related to the drug:

- A condition where you will feel weakness and fatigue of your hip and thigh muscles and an aching back caused by your body's immune system attacking your healthy cells and tissues.

SEROTONIN SYNDROME

The most common side effects include:

- Tremor
- Hyperreflexia (overactive or overresponsive reflexes)
- Spontaneous muscle spasms involving repeated, often rhythmic, contractions
- Muscle rigidity
- Temperature > 38°C (100.4°F)
- Ocular (eye) muscle spasms
- Agitation
- Sweating (diaphoresis)
- Muscle spasms associated with both agitation and/or sweating in combination

AUTOIMMUNE EVENTS

Although there is a chance that 1 in every 2 treated patients develops a side effect of any grade of severity due to the immune system attacking normal cells, about 17% of patients have a serious immune-related adverse event. Serious side effects may be fatal or threaten your life, require you to be hospitalized, may permanently disable you, and make you weak and unable to function at your current level, or may put your health at risk or require surgery or intervention by your study doctor.

These immune-related side effects have usually been controlled by stopping treatment and if needed, with medications, including steroids (medications that are used to decrease inflammation). If you develop an immune-related event, the symptoms may take several months to improve.

Immune-related adverse events observed in previous research studies using immunotherapies can include:

Stomach/Intestine: The most common stomach/intestinal side effect is diarrhea. Serious diarrhea/colitis has occurred in about 8% of patients receiving immunotherapy. Patients either had diarrhea alone or in combination with inflammation of the intestine associated with pain. Diarrhea due to treatment with ranges from mild to very severe with bleeding and, in very few cases, can be life threatening. Some cases of diarrhea have started out as mild and then become severe. About 1% of patients have had diarrhea or stomach/intestinal complications that required surgical removal of part of their intestine or resulted in death. Most of the other cases of diarrhea have been successfully treated by either stopping treatment and/or by giving an anti-diarrhea medicine or steroids. Rarely, treatment may cause constipation. You should tell your study doctor if you develop

any diarrhea, constipation, any change in your bowel movements, have blood in your stool, or have abdominal pain. Your study doctor may want to perform tests to better understand why you have these symptoms. These tests will allow your study doctor to look at your intestine for damage and figure out if you need additional treatment. You may also have to go to the hospital for additional tests and treatments.

If you know you have diverticulum (protrusions of the mucosa through the colonic wall) and/or diverticulitis (inflammation in the diverticulum), you need to tell your doctor and your doctor will evaluate whether it is appropriate to treat you with these medications.

Rash: has occurred in about 20% of patients taking these types of medications; most cases have been mild and less than 1% of cases have been serious. Some patients have had itching alone or together with the rash.

Eye: In rare cases, immunotherapy has caused inflammation in the various parts of the eye or with pigment (color) changes in the retina (a thin layer of tissue that lines the inside back wall of the eye). There have been no known cases of permanent eye damage but these conditions could interfere with your eyesight or even cause blindness if untreated. If these conditions occur, they may require treatment to reduce inflammation. In rare cases, double vision occurred as a result of muscle weakness. You should immediately tell your doctor if you think there is a change in your eyesight, develop double vision or if you develop eye pain while you are on this study.

Endocrine glands: Approximately 2% of patients taking immune medications have developed problems with particular glands (a gland is a group of cells or an organ that secretes a substance) such as the pituitary gland, the thyroid or the adrenal gland. Symptoms that may be associated with problems of the pituitary or adrenal glands include fatigue, confusion, weight loss, impotence (inability to perform sexually), and headache. Most of those symptoms were controlled using hormone therapy and steroids.

Liver: Approximately 4% of patients have developed serious problem with the liver as a result of treatment. Inflammation of the liver due to immunotherapy can range from mild to severe and in a very few cases, it can be life threatening. Acute liver failure resulting in death has occurred in less than 1% of patients. However, most severe cases have been successfully treated by stopping treatment and by administering anti-inflammatory medications such as steroids. You should contact your doctor if you experience symptoms that may be associated with problems of the liver that include fatigue, weakness, vomiting, nausea, and abdominal pain.

More frequent blood draws and a liver biopsy may be required if you develop serious liver abnormalities.

Other organs: Rarely, patients have developed problems in more than one organ system at a time such as liver, kidney, heart, muscles, blood vessels, and lung while taking immune medications. Acute failure of such organs resulting in death considered related to immune medications has occurred in about 1% of patients.

Meningitis (inflammation of the membrane surrounding the spinal cord and brain) has developed in less than 1% of patients treated with immunotherapy. This can cause headache, nausea and vomiting, stiff neck, and sensitivity of your eyes to light.

In very rare cases, immune-related motor neuropathy (inflammation of the nerves that control muscles) such as Guillain-Barre Syndrome may occur, which could be life-threatening if not treated appropriately. You should tell your doctor if you experience weakness of your limbs with or without numbness or tingling.

Nephritis (inflammation of the kidneys) has developed in less than 1% of patients treated with immunotherapy. The cases of meningitis and nephritis usually can be managed with treatment.

Vitiligo, a condition where the skin loses pigment and turns white, has occurred in less than 5% of patients. This condition is likely to be irreversible and permanent. Blistering and peeling of the top layer of skin resembling that of a severe burn have been rarely reported. It can be very severe resulting in death as in the case of toxic epidermal necrolysis.

In addition, immune-related reactions of any other organs, such as the joints, could also occur. This could cause pain and swelling. Joint pain has been reported by less than 1% of patients receiving immune medications. In rare cases, varying degrees of weakness of the voluntary muscles of the body have been reported and it is called Myasthenia Gravis.

You should tell your doctor or the research team immediately if you think you are developing any unusual side effects even if they weren't listed here.

You should not take any other medications, including non-prescription treatments such as aspirin, without the approval of your doctor.

ALLERGIC AND INFUSION-RELATED REACTIONS

All medications could potentially cause side effects, similar to an allergic reaction, that occur while it is being given into your vein or shortly after it is given. These

reactions could include symptoms such as fever and chills, skin rash, swelling, nausea, vomiting, headache, cold--like symptoms, difficulty breathing, or low blood pressure. These reactions could be mild or severe and might lead to death or permanent disability. If you experience these symptoms, your study doctor may slow down, interrupt, or even stop the delivery of pembrolizumab into your vein. Your study doctor may also give you some drugs to treat these symptoms.

For your safety, the study doctor will monitor you for these events. For example, for the first infusion you will have your vital signs measured before the infusion and after pembrolizumab administration is completed. If you are receiving pembrolizumab and experience a reaction that could be related to pembrolizumab, your study doctor may stop the infusion, and you may be withdrawn from the study.

OTHER POTENTIAL SIDE EFFECTS
In addition, there are other risks and possible discomforts you might experience from the study procedures, including:

Blood Draws: a blood draw may cause inflammation of the vein, stinging, discomfort, or pain; bruising; discomfort; redness; or bleeding at the site where the needle is placed to draw blood. You may feel dizzy or you may faint. There is a slight chance of infection.

ECG: Risks from an ECG can include skin irritation and/or a rash from the gel, or from wearing or removing the patches

Pregnancy: There may be known or unknown risks to a fetus or the pregnant woman, even if it is the man participating in the study. Detailed information about preventing pregnancy are given elsewhere in this document.

CT Scan Risks:
You will receive CT scans in this study. The CT scans are part of the normal care regardless the participation of this study. A CT scan will be performed according to standard practice, and is a computerized imaging procedure that makes many cross-sectional images (often called slices), both horizontally and vertically, of the body. For this study, the CT scan will be used to look at blood flow and the extent and activity of the cancer in your entire body. The scan will take about 30-60 minutes. You must not eat or drink anything for 4 hours before the test. You will need to remove all jewelry, piercings, and any other metal items from your body. A contrast dye called Omnipaque 350 (Iohexol) or Isovue 300 or 370 (Iopamidol) will be used for the scan to improve the quality of the images.

IT IS VERY IMPORTANT THAT YOU TELL THE INVESTIGATOR, RESEARCH TEAM, AND CT TECHNICIAN IF ANY OF THE FOLLOWING APPLY:

- You are or could be pregnant
- You have, or previously had, kidney problems
- You are taking Glucophage (metformin)
- You have any allergies to medications, contrast dyes, iodine, or shellfish
- You have a history of severe allergies
- You have recently taken or received barium ("barium study") or bismuth
- You have recently taken Pepto-Bismol, Kaopectate, Maalox, Bismatrol, or other digestive acids
- You have a cardiac pacemaker or any other biomedical device implanted, such as surgical clips, pins, screws, or metal plates in or on your body
- You have body piercings in or near your cancer
- You have ever worked in a metal or fabrication ship

In some cases, any of the listed above could mean that you should not have a CT scan performed.

A tourniquet will be applied to your arm or leg to help find a vein, and a contrast dye will be injected into a vein. The contrast agent does not contain any radioactivity, but instead, reacts with the x-rays to release a signal that is detected by the scanner. The pattern of the signal will provide the doctors with information about your cancer. You will be asked to lie still on a long narrow bench, or scanner bed, for up to 60 minutes. A strap and/or pillows may be placed around you to prevent movement so that the x-ray picture will be clear. The scanner bed you are on will slide into a large tunnel-shaped machine. You will be able to see the CT technician during the entire procedure, and there are microphones and speakers so you can communicate with the CT technician. You will also have a call button. You will be asked not to move during the scan and to relax and breathe normally. You may experience some discomfort or anxiety from being in the confined space. If this bothers you too much, the study team may be able to provide you with medication to help you stay calm. During the CT scan procedure, the scanner will rotate around you, and making clicking sounds, which is normal. Tell the CT technician if you start to feel unusual, especially if you have a flushing sensation, a salty or metallic taste in your mouth, a headache, and/or nausea/vomiting. These effects usually last for a few moments. Tell the CT technician immediately if you have any breathing difficulties, sweating, numbness, or heart palpitations. When the CT scan procedure and follow-up is finished, you may immediately resume your usual diet and activities.

You will review and sign a separate clinical informed consent document that describes the CT scan procedure in more detail at the time of the procedure itself.

MRI (Magnetic Resonance Imaging)

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for a certain amount of time while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is not unexpected and should not be painful. However, you may have the scan stopped at any time if this occurs.

If you have had a previous reaction to Gadolinium-based contrast agents or a history of severe allergies, please notify the operator/investigator. If you have kidney problems, please tell the operator.

It has been observed that deposits of Gadolinium-based contrast agent (GBCA) remain in the brains of some people who undergo four or more contrast enhanced MRI scans, long after the last administration. It is not yet known whether these Gadolinium deposits are harmful or can lead to adverse health effects. You should talk to the study doctor if you have any questions about the use of GBCAs with MRIs.

For Women of Childbearing Potential:
If you are pregnant, you may not participate in this study, because there is a potential risk that administration of pembrolizumab during pregnancy could cause harm to you and your unborn baby. Breastfeeding (nursing) mothers will not be included in this study, since it is not known whether the drugs in this study will be passed on to the baby in the mother's milk. If you are currently breastfeeding and wish to continue, your study doctor may recommend another treatment.

If you are a female of childbearing potential (able to become pregnant), you will be given a pregnancy test at no cost to you before beginning any study treatment.

Tell one of the study doctors right away if:

- You are pregnant
- You get pregnant
- You are breastfeeding

If you are a man:
We do not know what the experimental drug will do to your sperm. Should you get a woman pregnant, there could be harm to the unborn baby. You and your partner should use at least one effective birth control method (two are preferable when possible) if you are having sexual intercourse with a woman of childbearing potential.

For men and women:
Whether you are a man or a woman, there may be risks to your unborn children. If you take part in this study, you must use at least one effective birth control method (two are preferable when possible) as discussed with your study doctor. Examples of birth control methods include:

- Oral birth control pills
- Birth control patch
- Implanted (injectable contraceptive hormones or mechanical products such as intrauterine device)
- Barrier methods (diaphragm, condoms, spermicidal)
- Tubal ligation or vasectomy
- Abstinence

Certain birth control methods may not be a good choice for you (for example some patients with breast cancer should not use birth control methods that contain hormones). You should discuss the method of birth control which is best for you to use both during study treatment and for a period of time after treatment. Also, if you are a sexually active premenopausal woman or man the study staff will review your birth control use at each study visit. Use of contraception or abstinence should continue for a minimum of 1 month after completion of the study.

Please place your **initials** in the appropriate box below:

☐ I am surgically sterile (hysterectomy, tubal ligation or vasectomy) or have gone through menopause (no period for 24 consecutive months).

☐ I understand and agree to use contraception during treatment and for the time recommended by my doctor after treatment is over.

Whether you are a woman or a man, you should tell your doctor immediately if you become pregnant or if your partner becomes pregnant. The long-term effects of the study treatment on fertility are unknown. This means that it is unknown if treatment with these medications will affect your ability to have children in the future.

Required Tissue Sampling for Genetic Testing

Genes are in every cell of your body. Your genes carry instructions for the body to grow, develop, and survive. Genes are made of a substance called DNA. Most genes and DNA are identical among human beings, but there are small variations between different people. These small genetic differences are why people have their own unique characteristics, such as hair color, eye color, height, and other characteristics. Some traits affected by genetics are not visible, such why different people have different responses, including side effects to the same drugs. The proteins in your body were determined by your genes, and control how your body works. Differences in genes and therefore proteins can affect the way a disease develops, the way drugs act against the disease, or the way your body uses the drugs.

The testing of genes in a sample or biopsy is called genetic analysis. As part of the analysis on your samples, the investigators may do some genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, and

reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

The data from your sample that was used for genetic research will be used for research purposes only. The results of future studies could trigger the need to test or re-test the genetic research samples; therefore, the sample and data generated from them will be helped for many years (no time limit). These samples and data generated from them may be shared with other researchers, provided confidentiality is upheld. Although you will be told the results of study tests that are part of your medical care, the genetic testing described here will not be used for decisions about your medical care, and there may be no results from this genetic research for many years, therefore the results of the genetic testing may not be given to you, your doctor, or any other staff at the study center.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of any tests.

POTENTIAL BENEFITS

It is possible that your condition or health may improve because of your taking part in this study. However, we cannot and do not guarantee or promise that you will receive any benefits in any way. Information from this study may help other people in the future, including those with other cancers.

We cannot and do not guarantee or promise that you will receive any benefit from your participation in this study.

ALTERNATIVES

Before making the decision to participate in this research study you should discuss the important alternatives with your physician.

You do not have to be in this research study to receive treatment for your cancer. Alternatives to participating in this trial could include:

- Receive treatment using other drugs currently used in standard medical practice for your disease
- Participate in another research study should one be available
- Potentially receive radiation therapy should it be appropriate
- Receive palliative treatments. These types of treatments do not treat your cancer (i.e., are not curative) and only make you comfortable.

Possible alternative treatments and side effects of these treatments depend on the characteristics and type of your cancer. The effectiveness and side effects of other treatments may be different for different people. Your doctor will discuss with you the risks and benefits of any alternatives, including which other treatments might be suitable for you.

If you decide you not wish to take part in this study and wish to pursue any alternative, this will not change your regular medical care or the other treatment choices in any way.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate in this research study. Your questions should be answered clearly and to your satisfaction. If you decide not to participate at any time, tell any member of the research study staff.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this research study. After you hear about this information, you always have the right to withdraw from the study.

ClinicalTrials.gov

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.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Your identity and/or your personal health information will not be disclosed except as

authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford University, but if this happens, you will be identified only by a unique study identification number assigned to you upon entry on the study. Information about this number will be kept in a secure location and access limited to research study personnel only.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Epacadostat in combination with Pembrolizumab; the results will be provided to Merck, Incyte, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to obtain data or information on the safety and effectiveness of pembrolizumab in combination with epacadostat. The results will be provided to the Food and Drug Administration (FDA); and other federal and regulatory agencies as required

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

George A. Fisher, Jr., MD, PhD
Stanford Cancer Institute

875 Blake Wilbur Drive
MC 6562
Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- Medical records (from any doctor, hospital, or other healthcare provider).
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests, or other tests.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, George A. Fisher, Jr., MD, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Merck, including persons or companies working for or with the company
- Incyte, including persons or companies working for or with the company
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2030 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____ _____
Print Name of Adult Participant Date

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____ _____
Print Name of LAR Date

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

FINANCIAL CONSIDERATIONS

Payment
You will not be paid for your participation in this research study.

There is no reimbursement offered for any expenses related to your participation in this study.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.**

Participation in this study is not a substitute for health insurance.

Dr. George Albert Fisher is a paid advisor to Merck Co., Inc., the company sponsoring this study.

COMPENSATION FOR RESEARCH-RELATED INJURY

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. George A. Fisher, Jr. at (650) 498-6000. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (xxx) xxx-xxxx or toll free at 1-xxx-xxx-xxxx. You can also write to the Stanford IRB, Stanford University

If you are unable to reach anyone at the numbers listed above, and you feel that you may need immediate medical attention, call 911 or go the nearest emergency room.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and

- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) (e.g., parent, guardian or conservator) Date

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant (e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness (e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the POC must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*