

Consent and Authorization Form

COMIRB
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Study Title: A Phase II study of induction SBRT and olaparib followed by combination pembrolizumab/olaparib in gastric and gastroesophageal junction (GEJ) cancers

Key Information

Please read all the information below and ask questions about anything you don't understand before deciding if you want to take part.

You are being asked to be in a research study. Participation in Research is voluntary.

Purpose of the Study: We are doing this study to learn about the effectiveness of Stereotactic Body Radiation Therapy (SBRT) with Olaparib when given before the combination of pembrolizumab and olaparib (the study drugs) for metastatic gastric and GEJ cancers. The study drugs have each separately been FDA approved for treating other types of cancer, but the combination of the two drugs for your type of cancer is not FDA approved and is therefore considered investigational.

Procedures: If you agree to participate, the following will happen:

- You will have a screening visit to make sure you are eligible to be in the study. This will include MRI and/or CT scans as well as a tumor biopsy.
- If you are eligible and agree to participate:
 - You will visit the study doctor for radiation therapy on days 1-5 of Cycle 1 (each cycle is 21 days).
 - You will take olaparib by mouth twice daily.
 - Starting with Cycle 2, you will visit the study doctor for an injection of pembrolizumab every 3 weeks and have a tumor biopsy on day 1 of each cycle.
 - You will have MRI and/or CT scans every 9 weeks.
- You will be on study for one year.
- If you agree to participate, you will be asked to be in optional parts of the study.

Risks: Participation in research involves risks, including the following:

- Risks associated with radiation therapy include: fatigue; skin irritation; nausea, diarrhea, or bloating; lymphedema; abdominal pain; respiratory problems; decrease in liver or kidney function; weakened bones; or spinal cord injury
- Risks associated with olaparib include: decreased appetite, nausea, vomiting,

constipation, or diarrhea; headache, dizziness, fatigue, or weakness; high fever; anemia, decreased platelets, or decreased red or white blood cells; pain in abdomen, joints, muscles, back, or extremities; cough, congestion, or difficulty breathing; infection of respiratory tract or urinary tract; insomnia; swollen limbs; rash

- Risks associated with pembrolizumab include: infusion reactions; severe infection; fever; fatigue; abnormal levels of platelets or red or white blood cells in the blood; abnormal blood levels of salts, minerals, acids, fat, or sugar; gastrointestinal problems; damage to/changes in the function of the hormones/glands, immune system, liver, kidneys, or thyroid; skin problems; respiratory problems; pain; change in appetite or weight; nerve damage; swelling of limbs; inflammation of heart, blood vessels, brain, or spinal cord; vision problems; or multi-organ disease causing lesions
- Risks associated with tumor biopsy include: bleeding, infection, local nerve damage, pain from the needle sticks, and pain from aspirating the tumor with a syringe.

Benefits: There is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Alternatives: There may be other ways of treating your type of cancer, and you may be able to receive other treatments without participating in this study. Please discuss other treatment options with your doctor.

Detailed Consent

Why is this study being done?

The purpose of this study is to learn more about the effectiveness of Stereotactic Body Radiation Therapy (SBRT) with Olaparib when given before the combination of pembrolizumab and olaparib for metastatic gastric and GEJ cancers.

Pembrolizumab works by stimulating the immune system to target the cancer cells. Pembrolizumab is approved by the U.S. Food and Drug Administration (FDA) to treat your type of cancer.

Olaparib affects the way cells damaged by cancer work to repair themselves. Olaparib is a drug already approved by the FDA to treat certain other kinds of cancer.

Pembrolizumab and radiation therapy are separately considered standard of care for

your disease.

This is considered an “investigational” study, which means that this combination of drugs and radiation treatment has not been approved by the FDA. This study will examine if Olaparib and Pembrolizumab together, along with radiation, are effective in treating your particular type of cancer.

You are being asked to be in this research study because you have been diagnosed with a metastatic gastric and GEJ cancer, which is a type of tumor located near where your esophagus and stomach come together. Metastatic means the cancer has spread to multiple areas of your body.

How many people will participate in the study?

Up to 32 people will participate in the study in your area.

What happens if I join this study?

If you join the study, you will be asked to sign this consent form. You will be given a copy to keep and the original form will be kept at the clinic. You can withdraw from the study at any time and without giving a reason. This will not affect the standard of medical care you receive.

There are several parts to this study.

- Baseline Visit – At this visit screening procedures will be performed. If some of the procedures were completed within the previous 28 days, these may not need to be repeated
- Radiation Therapy – Once we have determined that you are eligible for participation, you will begin radiation therapy.
- Safety Run-In with Olaparib – On the same day that you begin radiation, you will begin treatment with olaparib.
- Olaparib & Pembrolizumab – Once you have completed radiation and olaparib alone, you will begin treatment with a combination of olaparib and pembrolizumab.
- Follow-Up: Two weeks after you have completed SBRT, you will receive a follow-up phone call. There will be additional follow-up procedures after you finish the study drugs.

There are also optional parts of this study. These optional procedures are voluntary and are not required. You can still take part in the main study if you choose not to take part in the optional study procedures. You will be given the choice later in this consent form to decide if you would like to take part in these optional procedures.

This next section is an overview of what you can expect if you take part in this study.

Study Procedures

You will be asked to have the following tests and procedures as part of this study. At the baseline visit, we will perform tests and procedures to make sure that you are eligible for this study. Please refer to the schedule of events later in this form to see which tests and procedures will be done at each visit.

While you are taking part in this study, many of the tests and procedures that will be performed are standard of care for your disease. Some “research” procedures are performed just for this study and are identified below.

- **Physical Examination:** A physical examination will be completed as part of your standard of care. We will also assess if the study intervention, SBRT, is affecting your body functions.
- **Medical and Cancer History**
Before you start the study, we will record your date of birth, race, ethnicity, and complete medical history. This history will look at the background and progress of your cancer and any treatments you have received for your disease.
- **ECOG Performance Assessment:** An assessment of how well you are able to carry out your day-to-day activities.
- **Review of Side Effects:** Some risks have been identified because of the disease process or through use of the study drugs themselves and these will be followed very closely by the Principal Investigator and study staff. More information will be provided in the Risk area of this consent.
- **Blood Collection:** Blood will be collected for routine testing over the course of the study. This will include pregnancy testing for women who can get pregnant.
- **Tumor Biopsy:** A biopsy is the removal of a tissue sample from a cancerous tumor for medical analysis. You will have three biopsies in this study. The biopsy will be either a core biopsy or a punch biopsy will be taken from your tumor. A numbing medication will be applied to the area of the biopsy before the procedure. In a core biopsy, a hollow needle is inserted through the skin into the tumor. A small “core” of tissue is removed using the needle. Your doctor may use ultrasound or x-ray equipment to guide the needle to the correct position. In a punch biopsy, a small circular blade is rotated through the skin into the tumor. A small sample of tissue is removed using the blade. This procedure leaves a small wound that is closed with sutures. For the first biopsy, archival tissue may be acceptable.
- **Urinalysis:** An analysis is a test of your urine that provides information about many bodily functions, such as your protein and nutrient levels, and whether you may be pregnant.

- **ECG:** This is a simple, noninvasive procedure that records the electrical activity of the heart. Electrodes are placed on the skin of the chest and connected in a specific order to a machine. Output usually appears on a long scroll of paper that displays a printed graph.
- **CT:** A computerized tomography scan (CT scan) is a series of detailed pictures of areas inside the body taken from different angles, focusing on your chest and abdomen.
- **MRI:** Magnetic resonance imaging is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body.
- **Pembrolizumab Administration:** You will receive pembrolizumab every 3 weeks at a dose of 200mg. This is the standard of care of for your disease.
- **Olaparib Administration:** While you are having radiation, you will take 200mg orally twice a day. Once radiation is finished, you will have 300mg administered orally twice a day.
- **Stereotactic Radiation Therapy (SBRT):** Subjects will be treated with 5 Gy per fraction for a total of 5 fractions totaling 25 Gy. You will receive RT on days 1-5.

Research Procedures

- **Blood tests:** Blood will be collected during the study to examine how your body and cancer responds to the combination of pembrolizumab, olaparib, and radiation treatment.

Study Visits

Trial Period:	Screening Phase	Treatment Cycles					End of Treatment	Post-Treatment	
Treatment Cycle/Title:	Study Screening	Day 1 Cycle 1	Day 8 Cycle 1	Day 15 Cycle 1	Day 1 Cycle 1+	Every 9 weeks	Discontinue	30 Day Safety Follow Up	Follow Up
Informed Consent and Medical History	x								
Review Medication and Side Effects	x	x	x	x	x		x	x	
Radiation		x							
Olaparib		x	x	x	x				
Pembrolizumab					x				
Physical Examination, Vitals, ECOG.	x	x	x	x	x		x	x	
Survival Status								x	x
Routine tests, including pregnancy tests.	x	x	x	x	x		x		
Coagulation tests	x	x			x		x		
Chemistry Panel Comprehensive Serum	x	x			x		x		
Urinalysis	x	x			x		x		
Thyroid tests	x				x		x		
ECG	x								
Tumor Imaging	x					x	x		x
Biopsy Tissue Collection	x				x				
Blood collection for research	x				x		x		

How long will I be in the study?

This study is expected to last for about one year.

What are the possible discomforts or risks?

Risks of RT:

As part of this study we will give you radiation therapy. Radiation therapy is a way of destroying cancer tissue while preserving as much of the surrounding healthy tissue as

possible.

You get some radiation from your environment. This procedure will give you radiation in much larger amounts than you would normally get from your environment. However, the radiation will be concentrated in areas where you have cancer.

By getting this therapy, you have some risk of developing a second type of cancer. The actual risk to you depends on many things, such as the amount of radiation you receive and how susceptible your cells are to radiation. These things are difficult to determine, but the risk of developing a second type of cancer is generally very low.

The actual amount of radiation you get from this procedure will depend on how large the cancer is and how many treatments you receive. Your doctor can tell you more about this.

Likely:

- Fatigue (all sites)
- Skin irritation (if target is in close proximity to the body surface)
- Nausea (if target is in close proximity to stomach)
- Diarrhea, bloating, gas (if target is in close proximity to intestines)
- Esophagitis (if target is in close proximity to the esophagus)

Less Likely:

- Lymphedema if target involves a lymph node or lymph node conglomerate.
- Pneumonitis and fibrosis if target is in or adjacent to the lung.
- Chest wall pain if target is adjacent to the chest wall.
- Transient pain exacerbation if baseline pain is present and attributable to the target lesion.

Rare, but serious:

- Brachial plexopathy if the target is in close proximity to the brachial plexus.
- Esophageal stricture if the target is in close proximity to the esophagus.
- Injury to the large airways or great vessels if the target is in close proximity to these structures.
- Change in function of abdominal organs, including decrease in liver or kidney function, which is unlikely to cause symptoms.
- Gastrointestinal ulcer that may cause abdominal pain and/or bleeding, and may require surgery.
- Bowel obstruction that may cause abdominal pain, nausea and vomiting, and may require surgery.
- Fistula development in the abdomen or pelvis, which may require surgery.
- Spinal cord injury in the treatment of vertebral lesions.
- Weakening of treated bones.

- Death

Risks of Olaparib

Olaparib works by helping cells damaged by cancer to repair themselves.

However, Olaparib can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects that may become serious or **life-threatening**, and in some cases, may lead to **death**.

VERY COMMON, SOME MAY BE SERIOUS (i.e. causing hospitalization, **life-threatening** or where noted, may cause **death**) – occurring in more than 20 people out of 100 people

- Nausea
- Fatigue
- Anemia (Low level of salt in the blood that may cause you to feel tired, confused, headache, muscle cramps or upset stomach)
- Vomiting
- Diarrhea
- Decreased appetite

COMMON, SOME MAY BE SERIOUS (i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) occurring in at least 5 out of 100 people but less than 20:

- Abdominal distension
- Abdominal pain
- Abdominal pain upper
- Joint stiffness
- Weakness
- Back pain
- Blood creatinine increased
- Constipation
- Cough
- Dizziness
- Altered taste
- Indigestion
- Difficulty breathing
- Headache
- Insomnia
- Muscle spasms
- Muscle pain

- Congestion
- Lowered white blood cell count
- Swollen limbs
- Pain in extremity
- High fever
- Rash
- Inflammation of the inside of the mouth
- Decreased platelet count
- Upper respiratory tract infection
- Urinary tract infection

UNCOMMON, SOME MAY BE SERIOUS - i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) – occurring in at least 1 to less than 5 people out of 100 people

- Vascular disorders: blood clots (Embolism), and blood clots in the lung (possible failure to breathe) (Pulmonary Embolism)
- Inflammation of the lungs which can cause shortness of breath and difficulty breathing. If severe, this can be life threatening. (Pneumonitis)

RARE, SOME MAY BE SERIOUS - i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) – occurring in less than 1 out of 1,000 people:

- Cancer of the bone marrow
- Disorder of blood cells in bone marrow
- Decreased red blood cell count and red blood cell abnormalities.
- High fever
- Hemoglobin decreased (decreased ability of blood to carry oxygen)
- Lymphocyte count decreased
- Drug- induced liver injury

This drug is being studied in combination with pembrolizumab, which means there is potential for increased frequency or higher severity of certain side effects.

Do not consume grapefruits or grapefruit juice while you are participating in this study. The FDA has found that grapefruit juice can allow more of some kinds of drugs to enter the blood and remain their longer, which may increase side effects.

Risks of Pembrolizumab

Pembrolizumab works by helping your immune system to fight your cancer.

However, pembrolizumab can also cause your immune system to attack normal organs and tissues in your body and can affect the way they work, which can result in side effects that may become serious or **life-threatening**, and in some cases, may lead to **death**.

VERY COMMON, SOME MAY BE SERIOUS (i.e. causing hospitalization, **life-threatening** or where noted, may cause **death**) – occurring in more than 20 people out of 100 people

- Itching of the skin
- Loose or watery stools
- Cough

COMMON, SOME MAY BE SERIOUS (i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) occurring in at least 5 but less than 20 people out of 100 people:

- Joint pain
- Rash
- Fever
- Back pain
- Abdominal pain
- Loss of skin color
- Not enough thyroid hormone so you may feel tired, gain weight, feel cold, have infrequent or hard stools
- Low level of salt in the blood that may cause you to feel tired, confused, headache, muscle cramps or upset stomach

UNCOMMON, SOME MAY BE SERIOUS - i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) – occurring in at least 1 to less than 5 people out of 100 people

- Inflammation of the lungs so you may feel short of breath and cough. Rarely this might lead to **death**
- Too much thyroid hormone so you may feel anxious, angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools
- Infusion reaction, where you may feel dizzy or faint, flushed, get a rash, have a fever, feel short of breath at the time of receiving your infusion (IV) or just after, or pain at the site of infusion
- Inflammation of the bowels/gut that can cause severe stomach pain with loose or watery stools, or stools that are black, tarry, sticky or stools with blood or mucus
- A condition called Stevens Johnson Syndrome (SJS) or Toxic Epidermal Necrosis (TEN). This condition involves inflammation of the skin, which may cause peeling of the skin, itchiness, and/or skin redness. The skin inflammation (i.e. peeling, itching and redness) could also be widespread throughout your

body. 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. These severe conditions can rarely lead to **death**.

RARE, SOME MAY BE SERIOUS (i.e. causing hospitalization, **life-threatening**, or where noted, may cause **death**) – in less than 1 out of 100 people

- 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 muscles so you may feel weak or have pain in the muscles, sometimes referred to as myasthenic syndrome
- Inflammation of the pancreas (a gland in your abdomen that controls sugar levels) Severe upper abdominal pain that may move to the back
 - Sick to your stomach
 - Vomiting that gets worse when you eat
- Inflammation of the eye
 - Redness of the eye
 - Blurred vision
 - Sensitivity to light
 - Have eye pain
 - See floaters
 - Have headaches
- Inflammation of the liver
 - Upset stomach and vomiting
 - Poor appetite
 - Feeling tired
 - Mild fever
 - Pain in the right side of your abdomen
 - Yellow eyes and skin
 - Dark urine
- Inflammation of the pituitary gland (a gland in the head)
 - Headaches
 - Upset stomach
 - Changes in behavior
 - Double vision
 - Few to no menstrual cycles
 - Weakness
 - Vomiting
 - Dizziness or fainting
- Adrenal glands (glands on top of the kidneys) may not produce enough hormone
 - Tiredness
 - Weight loss
 - Muscle weakness

- Feeling faint
 - Joint, muscle and belly aches
 - Nausea
 - Vomiting
 - Loose or watery stools
 - Fever
 - Salt craving
 - Darkening of the skin, like a suntan
- Type 1 Diabetes, a condition that can cause too much sugar in the blood which may make you:
 - Feel thirstier than usual
 - Frequent urination
 - Weight loss
 - May need regular insulin shots
- Inflammation of the kidney where you may:
 - pass less urine
 - have cloudy or bloody urine,
 - swelling
 - low back pain
- Inflammation of the middle layer of your heart (myocarditis)
 - Difficulty pumping blood throughout your body
 - Chest pain
 - Shortness of breath
 - Swelling of the legs
 - Fast or irregular heartbeat (that may cause dizziness or fainting)
 - **Death**
- Inflammation of the thyroid gland, an organ that makes and stores thyroid hormones. This condition may lead to change in your heart rate, blood pressure, body temperature, and metabolism (the rate at which food is converted into energy)
- A condition that may make you feel weak and tired and might have drooping of the eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing (myasthenic syndrome/myasthenia gravis including exacerbation)
- Formation of small clusters of immune cells (granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs
- Inflammation of the brain which may include:
 - Confusion
 - Fever
 - Headache
 - Disorientation,
 - Memory problems,
 - Seizures,
 - Changes in personality and behavior,
 - Difficulty speaking, weakness or loss of movement in some parts of your

- body, and loss of consciousness
- Inflammation of the spinal cord which may include:
 - Pain
 - Numbness
 - Tingling
 - Weakness in the arms or legs
 - Bladder or bowel problems including: needing to urinate more frequently; urinary incontinence; difficulty urinating; and constipation
 - Inflammation of the blood vessels: Symptoms will depend on the particular blood vessels that are involved in the inflammatory process, for example; if it is your skin, you may get a rash. If your nerves are not getting enough blood, you could have numbness and weakness. You may also experience fever, weight loss, and fatigue.
 - Low levels of parathyroid hormone (a hormone made by 4 tiny glands in your neck) which may result in:
 - Low blood calcium
 - Muscle cramps or spasms
 - Fatigue or weakness
 - Numbness, tingling or burning in your fingertips, toes or lips
 - Inflammation of the stomach (gastritis). You may have pain in your belly, feel full, or sick to your stomach. You may also experience nausea, vomiting or loss of appetite.
 - Low number of red blood cells (cells that carry oxygen) due to destruction of red blood cells (hemolytic anemia). You may feel weak, tired, lightheaded, short of breath, or have a fast heartbeat. You may also experience difficulty with physical exercise, pale or yellow skin, dark urine, or fever.
 - Not enough pancreatic enzymes (proteins that break down food) that leads to poor digestion of food (exocrine pancreatic insufficiency). You may have bloating, gas, discomfort in your belly, diarrhea, abnormal stool that is oily, or weight loss.
 - Inflammation of the protective sac surrounding your heart (pericarditis) which can cause sharp chest pain and shortness of breath (especially when lying flat), fever, and a fast or irregular heartbeat. In severe cases, your heart may have difficulty pumping blood throughout your body.

Additionally, since pembrolizumab was approved in September 2014, the following side effects have been reported by people receiving pembrolizumab. These side effects were voluntarily reported from a group of people of unknown size. It is not possible to estimate the frequency of these side effects:

- Inflammation of the joints which may include joint pain, stiffness, and/or swelling (arthritis)
- Severe responses of the immune system that cause the body to attack its own

blood cells, spleen, liver, lymph nodes, skin and brain. This may include fever, rash, inflammation of the liver, yellowing of the skin, an enlarged liver and spleen, low blood counts, and enlarged lymph nodes. The nervous system may also be affected and cause confusion, seizures, and even coma (hemophagocytic lymphohistiocytosis)

- Changes in eyesight, eye pain, whitish patches on the skin and hearing loss (Vogt-Koyanagi-Harada syndrome)
- Inflammation and scarring of the bile ducts (tubes that carry digestive fluid that is made in the liver). This can cause symptoms similar to those seen with inflammation of the liver (hepatitis) such as pain in right side of your belly, yellow eyes and skin, feeling tired, and itching (sclerosing cholangitis).
- Inflammation or swelling of the nerve fibers of the eye which send visual information from your eye to your brain. This health condition often has a sudden onset of vision loss, loss of color vision, pain when moving your eyes, and/or loss of peripheral vision. It may affect one or both eyes at the same time (optic neuritis).

Do not consume grapefruits or grapefruit juice while you are participating in this study. The FDA has found that grapefruit juice can allow more of some kinds of drugs to enter the blood and remain their longer, which may increase side effects

Risks of Having Blood Taken

In this study, depending on study visit, we will need to get blood from you over the course of the study. You may experience pain, bleeding, or bruising. There is a small risk of fainting and infection.

Risks of Having an IV Inserted in Your Vein

In this study we will insert a needle, connected to a plastic tube, into a vein in your arm. We will use the tube to take blood samples and to give you the study drugs and fluids. You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling, or bruising where the tube goes under your skin. In some cases, this type of tube can cause an infection where it goes under the skin. In rare cases, it can cause a blood clot in the vein. You will have this tube inserted for about 2-4 hours.

Computed Tomography (CT) Risk

As part of this study, we will perform a CT scan. CT is a way of taking detailed pictures inside your body by using X-rays. X-rays are a type of radiation.

You get some radiation from your environment. You get radiation from bricks and concrete, from some foods, and from radon gas, which is an invisible gas that seeps out of the ground. The amount of radiation that this CT scan will deliver to your body (give you) is about the same as you would get from living in your environment. This is an estimate. The amount of radiation you get could be higher or lower, depending on the

machine, the power setting, and your body weight. Exposure to radiation at high levels increases a risk of developing cancer. There is no evidence of such risks for these procedures.

There are also risks associated with the contrast materials used during this procedure. Contrast is given through an IV in the arm to enhance the images being taken. There is a rare possibility that you could have an adverse reaction to the contrast agent such as rash, hives, itching, mild headache and nausea.

Risks of Biopsy

In this study, if you agree to participate in the optional biopsy procedures, we will take 1 or 2 biopsies from you. There are some risks to taking a biopsy. There is a small chance that you could get an infection where the needle goes in. You may also experience redness, swelling, minor bleeding or bruising at the site where the cut was made or the needle inserted. You may experience mild to moderate pain at the site of the needle puncture. There is also a small chance that you could have an allergic reaction to the numbing medicine. After your skin heals up, you may have a small scar where we take the samples. If an X-ray is used to help place the needle, you will be exposed to additional radiation. The amount of radiation you receive during each biopsy procedure is approximately equal to the radiation you would receive in about 4 years in your normal environment.

The core biopsy procedure has some additional risks, depending on where your tumor is located. If you have a biopsy of a solid organ, like your liver or a kidney, or of a lymph node, there is a risk of pain, bleeding, and infection. There is a risk of damage to nearby structures or organs, and a small risk of tract seeding (spreading cancer along the tract that is created by the needle during the biopsy). There is a risk of injury due to positioning of the needle, and a small risk of heart or lung problems. If you have a lung biopsy, there is a risk of air getting into the space around your lung that would require a tube to be placed in between your ribs to draw the air out. If this tube is placed, some additional risks include damage to other nearby structures, including the lung, a prolonged air leak, and a possible need for additional tubes or procedures. There is a small risk of death from complications of a biopsy.

Risks of having an EKG

An electrocardiogram (EKG) is a test that records the electrical activity of the heart. Skin irritation is rare but could occur during an EKG from the electrodes or gel that is used.

Risks of Magnetic Resonance Imaging (MRI)

In this study we may take an MRI of your chest, abdomen, and pelvis. The MRI machine uses powerful magnetic waves to take pictures inside the body. The waves themselves are not harmful, but they can cause metal to heat up and electronics to stop working.

You should NOT have an MRI if you have metal or electronic devices inside your body. Heart pacemakers and insulin pumps are examples of electronic devices.

The MRI machine is a small round tube. It might make you uncomfortable if you do not like tight spaces.

The most common side effect of having an MRI is flashing lights in the eyes. This is caused by the magnetic waves and is not harmful. Some people also experience warmth and reddening of the skin. This usually goes away after a few minutes.

Other possible risks include:

Risk of Loss of Confidentiality

There is a risk that people outside of the research team will see your research information.

Reproductive Risks

The treatment or procedures involved in the study may involve significant risks to an embryo or fetus if you become pregnant during the study or within 120 days after it has ended. These risks include loss of the pregnancy or birth defects.

Be sure to discuss this with your physician if you are breast-feeding or plan to breast-feed within 120 days after the study ends, as use of the drugs involved in this study may result in significant, but little-understood side effects to you or your child.

Unknown Risks

The study may include risks that are unknown at this time. If during the course of this study, investigators discover a previously unknown risk likely to impact your health or decision to participate, the investigators will disclose those risks to you.

What are the possible benefits of the study?

You may or may not benefit from this study. This study is designed for the researcher to learn more about the combination of pembrolizumab and Olaparib when combined with radiation therapy in subjects with a specific form of unresectable or metastatic gastric and GEJ cancers.

Are there alternative treatments?

There may be other ways of treating your cancer than participating in this study. You should speak with Dr. Kim or another doctor about whether the following choices are available to you:

- Getting pembrolizumab, olaparib, and/or radiation therapy without being in this

- study
- Getting other treatment or care for your cancer without being in a study (surgery and/or chemotherapy)
- Taking part in another study
- Get treatment only for your pain and symptoms, but no treatment for the cancer itself, referred to as palliative or comfort care.
- Treatment by another doctor or at another facility.
- Get no treatment at all

You should talk to Dr. Kim and your doctor about your options. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

If you enroll in the study and later decide to stop participating, you can speak with Dr. Kim or another doctor about which non-study treatment options might be appropriate at that time.

Who is paying for this study?

This research is being sponsored by the University of Colorado Cancer Center, with support from Merck & Co., Inc. and Astrazeneca in the form of drugs used in the study.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

The funding for this study will pay for any tests or procedures that are related to the research study.

There are some medical procedures that you would get for your condition whether you were in this study or not, such as pembrolizumab, blood draws and tumor imaging. These are considered standard of care and will be billed to your health insurance. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs, or you do not have insurance, these costs will be your responsibility.

Ask your study doctor to discuss the costs that will or will not be covered by this research study. This discussion should include the costs of treating possible side effects. Otherwise, your participation in this study could lead to unexpected expenses for you.

Financial Disclosure: Dr. Kim has a significant financial interest due to her role as a speaker with Merck and Co. Dr. Kim is a PI on this study. Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc, is the sponsor of this study and the manufacturer of the study drug. Please feel free to ask any questions you may have about this matter.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury or experience an illness while you are in this study, you should call Sunnie Kim, MD, immediately. If the injury or illness requires immediate care, call 911, notify your treatment providers that you are participating in this study, and call Dr. Kim as soon as you are able. Dr. Kim's phone number is (303) 724-2520.

If you are participating at UCHealth Memorial Hospital (UCHealth Southern Colorado Region), please contact Dr. Hoyer immediately at (719) 365-6568.

If you have an injury that is caused by this research, we will offer to arrange medical care for you. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Sunnie Kim, MD. You may ask Dr. Kim or members of the study team any question about this study before enrolling, during it, or after it has concluded. Dr. Hoyer is the lead site researcher carrying out the study at UCHealth Southern Colorado Region (Memorial). Ask as many questions as you can when reviewing this form to help you make an informed decision about whether to participate. You may always call Dr. Kim at (303) 724-2520 or Dr. Hoyer at (719) 365-6568 with any questions, concerns, or complaints. You will be given a copy of this form to keep.

If you have concerns or complaints about the care Dr. Kim or others provide to you as part of this study, or questions about your rights as a patient and participant in research, you can always call the Institutional Review Board (COMIRB). COMIRB is an independent committee of scientists, physicians, and non-scientist community members charged with ensuring medical research is conducted ethically. You can call them at 303-724-1055.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This Web site will not include information that can identify you. You can search this Web site at any time by the title or investigator.

Optional study procedures

Here are the optional parts of this study. ***Remember, no matter what you decide to do about this optional part of the study, you may still take part in the main study.*** If you decide to withdraw your consent for the optional parts, you can continue to take part in the main study, unless you withdraw your consent for the main study as well.

Following each optional procedure is a statement asking if you want to participate in the optional procedure. Please read the statement and think about your choice. After reading the sentence, please check “Yes” or “No” and initial next to your choice. If you have any questions, please talk to your doctor or the study team member.

Optional consent for specimen banking for future research

Dr. Kim would like to keep some of the blood and tissue that is taken during the study but is not used for other tests. If you agree, the samples will be kept and may be used in future research to learn more about your cancer. The research that is done with your samples is not designed to specifically help you. It might help people who have your cancer and other diseases in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your samples will not affect your care.

The choice to let Dr. Kim keep the samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want him to use your samples any longer, and they will no longer be used for research.

When your samples are given to other researchers in the future, Dr. Kim will not give them your name, address, phone number or any other information that will let the researchers know who you are.

The samples and information collected for this study will be studied for the purposes described above. We intend to publish and share the results of this study. Your identity will be kept private when we publish and share our results. We will use and store your samples and information as long as they are useful, until you decide to stop participating, or until we close the study.

Sometimes samples are used for genetic research (about diseases that are passed on in families). Even if your samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your samples will only be used for research and will not be sold. The research done with your samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your samples include learning more about what

causes cancer and other diseases, how to prevent them and how to treat them.. There will be no cost to you for any sample collection and storage by Dr. Kim and the University of Colorado Denver.

We may share study data in public or restricted data banks so that the data may be used by other researchers. Your name and other information that could directly identify you will not be sent to data banks without your permission. Even though information that directly identifies you will not be shared, we cannot guarantee that no one will ever be able to use this information to identify you. Broadly sharing data in this way may involve risks to you or others that are unknown at this time.

Study samples and data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed. Future research could be about your condition or other related medical conditions. Other researchers may work for other universities, the government, or private industry.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your samples, you may still take part in the study.

I give my permission for my tumor tissue samples to be stored in a central tissue bank at the University of Colorado Denver for future use by the study investigators:

1. I give my permission for my tumor tissue samples to be kept by Dr. Kim for use in future research to learn more about how to prevent, detect, or treat cancer.

☐ Yes ☐ No _____ Initials

2. I give my permission for my tumor tissue samples to be used for research about other health problems (for example: causes of heart disease, osteoporosis, diabetes, etc.).

☐ Yes ☐ No _____ Initials

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Hospital
- UCHealth Southern Colorado Region
- UCHealth – Highlands Ranch Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Sunnie Kim
University of Colorado
Mail Stop 8117, Research One South
12801 E. 17th Avenue, Room 8116
Aurora, CO 80045

Robert Hoyer, MD
UCH-MHS Memorial Hospital Central
525 Bob Peters Grove
Colorado Springs, CO 80909

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Merck & Co., Inc. and Astrazeneca, the companies providing drugs for this study.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals; however, we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *some of the following health information about you that doesn't identify you* collected in this study available to:
QualTek Molecular Laboratories

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Billing or financial information

What happens to Data and Blood that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and blood collected from you during this study are important to this study and to future research. If you join this study:

- The data and blood given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and blood collected from you.

- If data or blood are in a form that identifies you, UCD and the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- You will have no rights or financial interest in any product or idea resulting from this study or any future study that involves your samples or information.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I have been told about the possible risks and benefits of this study. I authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____

A signature line for a witness is required for consent of non-reading subjects and consent using a short form.

Witness Signature: _____

Date: _____

Witness Print Name: _____

Witness of Signature Y

Witness of consent process Y