Participant Informed Consent for Clinical Research

Study title for participants: A Study of Pembrolizumab and Olaparib for People with Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency or Exceptional Treatment Response to Platinum-Based Therapy

Official study title for internet search on http://www.ClinicalTrials.gov: A Phase 2 Trial to Evaluate the Safety and Antitumor Activity of Pembrolizumab and OLApaRib (POLAR) Maintenance for Patients with Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency and/or Exceptional Treatment Response to Platinum-Based Therapy

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If you are the legally authorized representative (LAR) of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to the study participant.

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this study because you have a type of cancer called pancreatic ductal adenocarcinoma (PDAC) or acinar cell carcinoma. The cancer has spread outside your pancreas (metastasized) and it has a genetic mutation (change) called HRD (homologous recombination deficiency), and/or the cancer has had an exceptional response to platinum-based chemotherapy for more than 6 months.

The study researchers think that combining the drugs pembrolizumab and olaparib (POLAR) may help people with your disease because pembrolizumab activates the immune system to fight cancer, and olaparib destroys cancer cells by preventing them from repairing damage to the genetic information that helps them survive and grow. We are doing this study to find out whether combining these drugs may be a more effective treatment for your cancer than taking olaparib alone.

The US Food and Drug Administration (FDA) has approved pembrolizumab to treat some forms of cancer, but not your cancer, and its use in this study is considered investigational. Olaparib has been approved to treat your cancer, but combining olaparib with pembrolizumab is considered an investigational use of the drug.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my metastatic PDAC with HRD?

People who are not in a research study are usually treated with chemotherapy, olaparib (alone), or with a treatment break (taking some time off from receiving treatment). Sometimes combinations of these treatments are used, and your doctor can explain which combination may be best for you. These treatments can reduce symptoms and may stop your tumor from growing for several months or longer.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available
- You may choose not to be treated for cancer
- You may choose not to be treated for cancer, but to receive comfort care to help relieve your symptoms

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive treatment with pembrolizumab every 3 weeks, as an intravenous (IV) infusion through a needle placed in a vein in your arm. Olaparib is a tablet that you will take by mouth, twice a day. After the first 6 months of treatment (nine Cycles), the pembrolizumab will be increased to a higher dose and will be given on a 6 week schedule, you will continue to take olaparib twice a day for up to 4 years.

If your disease gets worse (progresses) during the study, or if you are not able to tolerate the side effects of the study drugs, you will stop treatment and come to the clinic for an End-of-Treatment visit. About 30 and 60 days after your last dose of the study treatment, you will come for a follow-up visit so that the study doctor can check for side effects. We will continue to follow your condition every 12 weeks for 5 years, either during your clinic visits or with a phone call.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study, there is a risk that the study treatment may not be as good as the usual approach at shrinking or stabilizing your cancer.

There is also a risk that you could have side effects from the study drugs. These side effects may be worse, and they may be different than you would have with the usual approach.

Some of the most common side effects that the study doctors know about are:

- Tiredness, lack of energy (fatigue)

- Itching of the skin
- Loose or watery stools
- Cough
- Feeling sick to your stomach (nausea)
- Vomiting

There may be some risks that the study doctors do not yet know about.

Benefits

The study treatment has been shown to shrink your type of cancer. It is not possible to know now whether the study treatment will extend your time without disease compared with the usual approach. Your cancer may get better, or it may stay the same or get worse. What we learn from this study may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

1. Your health changes, and the study is no longer in your best interest
2. New information becomes available, and the study is no longer in your best interest
3. You do not follow the study rules
4. For women who are able to have children: You become pregnant while you are in the study
5. The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), the US Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

We are doing this study to find out whether combining the drugs pembrolizumab and olaparib (POLAR) is a safe and effective treatment for people who have metastatic PDAC with an HRD mutation. We will also see whether POLAR works as well as the standard treatments for your cancer, which include chemotherapy, olaparib (alone), or taking some time off from treatment (treatment break).

Pembrolizumab is an antibody, like the proteins made by the immune system to protect the body from harm. Pembrolizumab blocks the protein PD 1 (programmed cell death receptor 1) that usually acts as a "brake" on the immune system. Blocking this protein is like releasing the brakes, so that the immune system can target cancer cells and destroy them. Pembrolizumab has been approved by the FDA to treat several different cancers, but it has not been approved to treat your cancer, and its use in this study is considered investigational.

Olaparib is a type of medication called a PARP (poly ADP ribose polymerase) inhibitor. PARP is a protein that helps repair damage to DNA, the genetic material that serves as the body's instruction book. Changes (mutations) in DNA can cause cancer cells to grow quickly and out of control. But PARP inhibitors have been shown to prevent PARP from working, so cancer cells can't repair themselves, and they stop growing. The FDA has approved olaparib as a treatment for your cancer, but combining olaparib with pembrolizumab is an investigational use of the drug.

The pembrolizumab and olaparib used in this study will be provided by Merck & Co.

About 63 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

All study participants will receive the same study treatment: IV infusions of pembrolizumab every 3 weeks, and olaparib by mouth twice a day for the first 6 months (nine 21-day treatment Cycles). After that, the pembrolizumab will be increased to a higher dose and will be given on a 6 week schedule and continue to take olaparib twice a day for up to 4 years.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Collection of blood samples (about 13 teaspoons total) for research tests:
  - Immune cell profiling test to see how your immune cells work
  - ctDNA (circulating tumor DNA) test: ctDNA is genetic material from dying tumor cells that is released into the blood. Measuring ctDNA may lead to a less invasive way to screen for genetic mutations in tumors.
  - CEA and Ca19-9 tests: CEA and Ca19-9 are tumor markers that show how your disease is responding to the study treatment
  - Biomarker test to see how your immune system and your genes/cells are responding to the study treatment: A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.

- We will study your samples to improve our understanding of the way changes in genes can affect the risk of cancer and other diseases. Genes are the “blueprints” for our bodies. Sometimes genes may have changes that occur during your lifetime that can affect the way a gene works. These changes (mutations) may cause cells to grow rapidly and abnormally, and become a cancer that you cannot pass on to your family members (somatic mutation). However, some people develop cancer because they were born with a mutation in a gene. People who develop cancer because of a genetic mutation usually inherit this genetic change from their mother or their father (germline mutation). Other family members (brothers, sisters, and children) may share this same mutation. Most people with cancer did not develop their disease because of an inherited mutation.
- We will look for changes in your genes using a test called Whole Genome Sequencing or Whole Exome Sequencing (WGS/WES). Your data may be used to learn more about cancer and other diseases. Data from large numbers of people can help researchers learn how changes in the order (sequence) of genes might affect a disease or a person’s response to treatment, identify possible links between diseases, and provide new ideas for drug development and personalized therapies.
- ECG (electrocardiogram) to measure the electrical activity of your heart
- Blood or urine pregnancy test, in women who can have children. You must have a negative pregnancy test throughout the study.
- Collection of a sample of your tumor tissue: If you have stored (archival) tissue samples from an earlier biopsy or surgical procedure, the study doctor will request a portion of the stored tissue from the hospital or medical center where the procedure was performed. If you do not have stored tumor tissue available, you will be required to have a biopsy procedure to take part in this study. The doctor performing the biopsy will explain the risks of the procedure. You will sign a separate consent form before the biopsy procedure.

During the study:

You will receive an intravenous (IV) infusion of pembrolizumab through a needle placed in a vein in your arm, every three weeks.

Olaparib is a tablet that you will take by mouth, twice a day, every day of each 21-day treatment Cycle. You can take olaparib with or without food. Swallow the tablets whole; do not chew, break, or dissolve them in water. Keep taking olaparib as instructed by your doctor or other health care provider, even if you feel well.

A member of the study team will give you a pill diary, so that you can write down, twice a day, when you take olaparib. Instructions about how to take the drug are included in the diary. Bring your completed diary to all your study appointments, and bring your medication bottle(s), even if the bottle is empty.

After the first 6 months of treatment (nine 21-day treatment Cycles) then the pembrolizumab will be increased to a higher dose to be given on a 6 week schedule and continue to take olaparib twice a day for up to 4 years, or until your disease gets worse (progresses).

<u>Exams, Tests and/or Procedures</u>

You will have exams, tests, and procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Tumor biopsy procedure between weeks 6 and 9

- Collection of blood samples (about 13 teaspoons each time) for research tests at the time of your biopsy procedure and during Cycles 6, 12, and 18 (if your doctor thinks the tests are necessary):
  - Immune cell profiling test
  - ctDNA test
  - Biomarker test
  - CEA and Ca19-9 tests
- CT scans to assess your disease, every 9 weeks until Cycle 10, then every 12 weeks until you complete the study treatment

End-of-Treatment and follow-up visits:

On the day that you receive your last infusion of pembrolizumab, you will have an End-of-Treatment visit in the clinic. The study doctor and study team will check to see if you are having any side effects and perform the following tests for research purposes:

- Collection of blood samples (about 13 teaspoons total) for research tests:
  - Immune cell profiling test
  - ctDNA test
  - Biomarker test
- Blood pregnancy test in women who are able to have children
- CT scan to assess your disease
- Tumor biopsy procedure

About 30 days after your last dose of either pembrolizumab or olaparib (whichever is last), you will come for a follow-up visit so that the study doctor can check for side effects of the study treatment. We will continue to follow your condition every 12 weeks for 5 years, during your follow-up visits in the clinic or with a telephone call.

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?

You will not receive the results of any tests, including genetic tests, done for research purposes during this study. If you or your family are interested in learning more about inherited risk factors for cancer, ask your study doctor for a referral to MSK's Clinical Genetics Service.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- There may be a risk in finding out new genetic information about yourself. New health information about inherited traits that might affect you or your family (blood relatives) could be found during a research study.

The drugs used in this study may affect how different parts of your body work, such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood throughout the study, and he or she will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it difficult for you to have children.
- Some side effects may be mild. Others may be very serious, and may even result in death.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce your side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of pembrolizumab:

Common, some may be serious In 100 people receiving pembrolizumab, more than 20 and as many as 100 may have:
• Itching of the skin • Loose or watery stools • Cough

Occasional, some may be serious In 100 people receiving pembrolizumab, between 5 and 20 may have:
• Joint pain • Rash • Fever • Back pain • Pain in the belly • Loss of skin color • Not enough thyroid hormone (hypothyroidism), which may make you feel tired, gain weight, feel cold, or have infrequent or hard stools • Low levels of salt in the blood (hyponatremia), which may make you feel tired, feel confused, have a headache, have muscle cramps, and/or feel sick to your stomach • Inflammation of the lungs (pneumonitis), which may make you feel short of breath and cough

Occasional, some may be serious In 100 people receiving pembrolizumab, between 5 and 20 may have:
• Too much thyroid hormone (hyperthyroidism), which may make you feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, or have loose and watery stools • Infusion-related reaction (IRR; like an allergic reaction), which may make you feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, experience a decrease in your blood pressure, or have pain at the infusion site, either while you are receiving the infusion or just after • Inflammation of the bowels/gut (colitis), which may cause severe pain in your belly, with loose or watery stools, and black, tarry, sticky stools, or stools with blood or mucus • Severe inflammation of the skin (Stevens-Johnson syndrome and/or toxic epidermal necrolysis), which may cause peeling of the skin, itchiness, and/or skin redness. The skin inflammation could be widespread throughout your body. More severe skin reactions may involve the inside of your mouth, the surface of your eyes and genital areas, and/or may cause the top layer of skin to peel from all over your body, which can cause a severe infection.

Rare, and serious In 100 people receiving pembrolizumab, between 1 and 5 may have:
• Inflammation of the nerves (Guillain-Barré syndrome), which may cause pain, weakness or tingling in your hands and feet, and may spread to your legs, arms, and upper body, leading to severe muscle weakness and possible temporary paralysis • Inflammation of the muscles (myositis), which may make you feel weak or have pain in your muscles • Inflammation of the pancreas (a gland in your abdomen that controls sugar levels; pancreatitis), which may cause severe pain in the top part of your belly, and the pain may move to your back; you may feel sick to your stomach, and experience vomiting that gets worse when you eat • Inflammation of the eye (uveitis), which may cause eye redness, blurred vision, sensitivity to light, eye pain, headaches, or seeing “floaters” • Inflammation of the liver (hepatitis), which may make you feel sick to your stomach and vomit, feel like not eating, feel tired, have a mild fever, have a pain in the right side of your belly, yellow eyes and skin, and dark urine • Inflammation of the pituitary gland (a gland in the head; hypophysitis), which may make you feel sick to your stomach or have headaches, changes in your behavior, double vision, few to no menstrual cycles, weakness, vomiting, and dizziness or fainting • Adrenal glands (glands on top of the kidneys) may not make enough hormone (adrenal insufficiency), which could cause tiredness; weight loss; muscle weakness; feeling faint; having joint, muscle, and belly aches; nausea; vomiting; and loose or watery stools; fever; salt craving; and sometimes darkening of the skin like a suntan

Rare, and serious In 100 people receiving pembrolizumab, between 1 and 5 may have:
• Type 1 diabetes, a condition that can result in too much sugar in your blood, making you feel thirstier than usual, with frequent urination, and weight loss. You are likely to need regular insulin shots to treat this condition. • Inflammation of the kidney (nephritis), which may make you pass less urine or have cloudy or bloody urine, swelling, and low back pain • Inflammation of the middle layer of your heart wall (myocarditis), which may make it difficult for your heart to pump blood through your body, causing chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting. • Inflammation of the thyroid gland, which may lead to changes in your heart rate, blood pressure, body temperature, and the rate at which food is converted into energy (thyroiditis) • Myasthenic syndrome/myasthenia gravis including exacerbation, conditions that may make you feel weak and tired, and may cause drooping eyelids, blurred or double vision, difficulty swallowing, slurred speech, weakness in your arms and legs, or difficulty breathing • Sarcoidosis, the 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 (encephalitis), with confusion and fever. Symptoms may include disorientation, memory problems, seizures (fits), 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 (myelitis), which may cause pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, and constipation

Possible side effects of olaparib:

Common, some may be serious In 100 people receiving olaparib, more than 20 and as many as 100 may have:
• Feeling sick to your stomach (nausea) • Vomiting • Tiredness/weakness (fatigue) • Indigestion/heartburn (dyspepsia) • Loss of appetite • Headache • Changes in the way food tastes (dysgeusia) • Dizziness • Loose or watery stools (diarrhea): Call the study doctor right away if you have continuous or severe diarrhea • Cough • Shortness of breath (dyspnea)

Common, some may be serious In 100 people receiving olaparib, more than 20 and as many as 100 may have:
• Decrease in the number of red blood cells (anemia), which can be associated with shortness of breath, fatigue, pale skin, or fast heartbeat, and may require a transfusion for treatment • Decrease in the total number of white blood cells (leukopenia) and in white blood cells called neutrophils (neutropenia) that protect you from infection, which can be associated with fever

Occasional, some may be serious In 100 people receiving olaparib, between 4 and 20 may have:
• Sore mouth (stomatitis) • Skin rash • Increase in the level of creatinine in the blood. This test result can suggest a potential problem with your kidneys. Symptoms of kidney damage include decreased urine output, swelling of your legs, ankles, and feet from retaining fluids, unexplained shortness of breath, fatigue, nausea, confusion, and chest pain. • Pain in the stomach area under the ribs (upper abdominal pain)

Rare, and serious In 100 people receiving olaparib, 3 or fewer may have:
• Allergic reactions; symptoms include tingling or itching in the mouth, hives, swelling of the lips, face tongue, throat, and other parts of the body, wheezing, nasal congestion, trouble breathing, abdominal pain, diarrhea, nausea, or vomiting • Itchy rash or swollen, reddened skin (dermatitis) • Increase in the size of red blood cells (not associated with any symptoms); this condition is treatable but, in rare cases, a blood transfusion may be required

Possible risks of radiation-based diagnostic imaging: You will be exposed to low amounts of radiation from the imaging procedures performed during this study. The CT scans provide detailed pictures of the inside of the body, like an MRI (magnetic resonance imaging) scan, but using radiation, like an X-ray. Every day, people are exposed to low levels of radiation that comes from the sun and the environment. Scientists think that exposure to too much radiation can be harmful. The amounts of radiation associated with the scans included in this study are comparable to those from standard-of-care imaging procedures. Each year, many thousands of patients routinely undergo similar diagnostic procedures and receive comparable radiation doses with no short- or long-term adverse effects.

Possible risks of contrast materials: Iodine-based contrast materials, also called contrast agents or contrast media, are injected into a vein in the arm to improve the pictures produced by CT scans and MRI scans. Contrast materials are generally very safe, but adverse reactions ranging from mild to severe may occur. Serious allergic reactions or other reactions are rare. A small percentage of patients may develop a delayed allergic reaction, with a rash that can occur hours to days after the injection of the contrast agent. Most of these rashes are mild, but severe rashes may require medication; please discuss any reactions the study doctor.

Reproductive risks: You should not get pregnant, breastfeed, father a baby, or donate sperm while you are in this study. The study drugs used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while you are in this study. You must continue to use these methods for 120 days after completing the study treatment.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study
- Do not eat grapefruit or Seville oranges, or drink the juice of these fruits, while you are receiving the study treatment. These foods may affect the way the study drugs work.
- Remember to bring your completed pill diary to all your clinic appointments, along with your medication bottle(s), even if the bottle is empty.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK) and funded by Merck & Co. Several of the investigators involved in this study receive extra money from Merck for outside activities with the company. These activities may include consulting, serving on advisory boards, giving speeches, or writing reports.

If you would like to know more about the steps MSK has taken to protect your best interests while you are in this study, please contact the MSK Patient Representative Department at 212-639-7202.

What are the costs of taking part in this study?

You will not have to pay for the pembrolizumab and olaparib, or for tests and procedures done only for research purposes, as described above in *What extra tests and procedures will I have if I take part in this study?* These tests and procedures include:

- Collection and testing of archival tumor tissue
- Tumor biopsy procedures
- Collection and testing of blood samples for research purposes
- CT scans to assess your disease

It is possible that pembrolizumab and olaparib may not continue to be supplied while you are in the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your cancer while you are in this study. These charges include the costs of insurance co-pays and

deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Although you do not have to pay for the pembrolizumab, the cost of getting it ready and giving it to you is not paid by the study sponsor, so you or your insurance company may have to pay for this.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

Your biospecimens (blood, tissue) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may

be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

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

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

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, long-term care insurance, or if you are a member of the military, or receive your health care through TRICARE, the Federal Employees Health Benefits Program, the Veterans Health Administration, or the Indian Health Service.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

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

A Study of Pembrolizumab and Olaparib for People with
Metastatic Pancreatic Ductal Adenocarcinoma and Homologous Recombination Deficiency
or Exceptional Treatment Response to Platinum-Based Therapy

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Wungki Park, MD and Eileen M. O'Reilly, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases

- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- The company or organization that provides the funding for the study, Merck & Co.
- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study drugs.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

Study Calendar: This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

Trial period	**Screening**	**Treatment Cycles (21 Day Cycles)**										**End of Treatment**	**Post-treatment**	
Treatment Cycle/ Part of study	Pre-screening (Visit 1)	1	2	3	4	5	6	7	8	9	10 and beyond	After stopping the study drugs	Follow-up in Clinic (30 and 60 days post-treatment)	Long-term follow-up (every 12 weeks)
Pembrolizumab administration		X	X	X	X	X	X	X	X	X	X (Even Cycles ex. 10, 12, etc.)			
Olaparib		By mouth, twice a day												
Review side effects		X	X	X	X	X	X	X	X	X	X (Even Cycles)	X	X	X
Physical exam, medication review, vital signs	X	X	X	X	X	X	X	X	X	X	X (Even Cycles)	X	X	
Pregnancy test	X	X												
Collection of blood for standard tests	X	X	X	X	X	X	X	X	X	X	X (Even Cycles)	X		
CA 19-9, CEA tests	X	X	X	X	X	X	X	X	X	X	X (Even Cycles)	X		
ECG	X			X			X			X	X (Even Cycles)			
Urinalysis	X			X			X			X	X (Even Cycles)			
Tumor imaging	X			X			X			X	X (Every 12 weeks)	X		
Biopsy procedure	X			X								X		
Collection of blood for research tests	X			X			X				X (Cycle 12 and 18)	X		
During visits or with a phone call														X