

MC230404 / 23-009036

Photodynamic Priming to Facilitate Immunologic Activity of Anti-PD1 in Patients with Pancreatic Cancer

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC230404 Photodynamic Priming to Facilitate Immunologic Activity of Anti-PD1 in Patients with Pancreatic Cancer

IRB#: 23-009036

Principal Investigators: Vinay Chandrasekhara, M.D., Ryan Carr, M.D., P.H.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see whether verteporfin can help endoscopic ultrasound-guided (EUS-guided) photodynamic therapy (PDT) target your tumor, and to study the effects of pembrolizumab in combination with PDT plus standard of care chemotherapy (FOLFIRINOX). You have been asked to take part in this research because you have been diagnosed with pancreatic cancer that is advanced or has spread to other parts of your body (metastatic cancer).
What's Involved	Study participation involves about the same amount of time as regular care for your cancer. Procedures include: • Receiving verteporfin, which lights up your tumor to help PDT target your tumor (EUS-guided PDT)



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	• Receiving treatment with pembrolizumab plus standard chemotherapy through a vein in your hand or arm You will need to stay in the hospital for a couple of days after PDT because you will be very sensitive to light. Pembrolizumab is given every 6 weeks for up to 17 cycles. Standard cancer therapy with FOLFIRINOX for pancreatic cancer is given every other week. You will be asked to have blood drawn (about two teaspoons) for research purposes at several timepoints. We will draw the research blood at the same time as blood draws for your regular care. You will be asked to have up to two biopsies for research – one during the PDT procedure before you receive verteporfin, and, if you are eligible, the other about 2 days later after you start therapy with pembrolizumab and before you start chemotherapy with FOLFIRINOX. After you finish treatment with pembrolizumab, we will follow your health for up to 3 years.
Key Information	The main risks of the study are from the study drugs being used to treat your cancer. Verteporfin and pembrolizumab are “investigational” which means they have not been approved by the FDA for treating pancreatic cancer. The FDA has approved the use of verteporfin and pembrolizumab for this study. Verteporfin is generally well-tolerated with the most common side effects being discomfort or pain at the injection site, or rash near or around the injection site. You will be sensitive to light for a couple days after the PDT procedure. The most common side effects of pembrolizumab are itching of the skin, watery stools, and cough. The risks associated with study participation are completely described later in this form. Be sure to review the risks carefully.



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	There are alternatives to taking part in this research. The research team will discuss the other treatment options with you. Most of the costs of this study are paid by the research study, including the cost of the study medications. The costs are described in detail later in this form. Be sure to review them thoroughly. It is not known whether this treatment will be better or worse for you than what your doctor would normally choose. By participating in this research study, you may help doctors answer this question.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.



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Contact Information

If you have questions about ...	You can contact ...
- Study tests and procedures - Materials you receive - Research-related appointments - Research-related concern or complaint - Research-related injuries or emergencies - Withdrawing from the research study	Principal Investigator(s): Dr. Vinay Chandrasekhara Dr. Ryan Carr Phone: (507) 284-2511 Institution Name and Address: Mayo Clinic 200 First St SW Rochester, MN 55905
Rights of a research participant	Mayo Clinic Institutional Review Board (IRB) Phone: (507) 266-4000 Toll-Free: (866) 273-4681
- Rights of a research participant - Any research-related concern or complaint - Use of your Protected Health Information - Stopping your authorization to use your Protected Health Information - Withdrawing from the research study	Research Participant Advocate (RPA) (The RPA is independent of the Study Team) Phone: (507) 266-9372 Toll-Free: (866) 273-4681 E-mail: researchparticipantadvocate@mayo.edu
Billing or insurance related to this research study	Patient Account Services Toll-Free: (844) 217-9591

Other Information:

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.

There will also be a description of this research study available on <http://www.clinicaltrials.mayo.edu>. This website will not include information that can identify you. You can search this website at any time.



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Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have advanced or metastatic pancreatic cancer that cannot be surgically removed.

The plan is to have about 25 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to gather information on the safety of verteporfin (photodynamic primer (PDP)), which is used to light up your tumor. PDP may help pembrolizumab (immunotherapy) plus FOLFIRINOX (chemotherapy) to better target your tumor.

Verteporfin and pembrolizumab are “investigational.” Investigational means that the U.S. Food and Drug Administration (FDA) has not approved verteporfin or pembrolizumab for the treatment of pancreatic cancers, although they are allowing them to be used in this study.

Information you should know

Who is Funding the Study?

This study is being funded by the National Institutes of Health/National Cancer Institute and the Mayo Clinic Comprehensive Cancer Center.

Merck & Co. is providing pembrolizumab (KEYTRUDA®) for this study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.



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How long will you be in this research study?

You may receive treatment in this research study for up to 2 years, or until your cancer stops responding or gets worse or you cannot tolerate the side effects.

After you complete treatment, we will follow your health for up to five years. We may review your medical records, telephone you, or send you a request for information through email or the patient portal.

What will happen to you while you are in this research study?

Pre-Study Screening

Before you can take part in this study, you will need to have the following tests and procedures to find out if you can be in the study:

- Medical history and physical exam including performance status (assessment of your activity level), height, and weight
- Routine blood testing including tests for your cancer and pregnancy testing (if you are able to become pregnant)
- Routine imaging of your cancer

These exams, tests or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This decision will be up to the Principal Investigator.

Prior to PDT

If you are eligible and enrolled in the study, you will have the following research tests and procedures prior to the endoscopic ultrasound procedure:

- Quality of Life questionnaire
- Research blood samples (about 50 mL or about 3.5 tablespoons)

Endoscopic ultrasound (EUS)-Guided Photodynamic Therapy (PDT)

You will have a procedure called “endoscopic ultrasound (EUS)-guided photodynamic therapy (PDT)” before you begin treatment. You will need to check into the Clinical Research and Trials Unit (CRTU) at Mayo Clinic Hospital prior to your procedure.



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The EUS-guided PDT procedure is an outpatient procedure. You will be given a photodynamic primer (PDP), called verteporfin, through an intravenous (IV) catheter inserted in your arm. The verteporfin will help the PDT target your tumor.

During the PDT procedure, you will also have the following tests and procedures:

- Routine imaging of your cancer
- Research blood samples
- Oral swab to assess verteporfin levels
- Research biopsy

After the PDT procedure, you will need to stay in the hospital (CRTU) for a couple days because you will be sensitive to light.

Before beginning treatment with pembrolizumab and FOLFIRINOX, you will have the following tests and procedures:

- Medical history and physical exam
- Routine blood testing
- Questionnaire and patient diary
- Research blood samples (about 50 mL or about 3.5 tablespoons)

Pembrolizumab and FOLFIRINOX Therapy

About 1-3 days after your PDT procedure, you will begin pembrolizumab. Pembrolizumab is given by intravenous (IV) infusion through a vein in your hand or arm or a port if you have one.

There will be up to 9 cycles of treatment for this study. Each cycle is 6 weeks. You will receive pembrolizumab on Day 1 of each cycle.

In addition, you will have standard chemotherapy with FOLFIRINOX by intravenous (IV) infusion for about 6 months. The first cycle will be given 2-5 days after you have completed PDT and pembrolizumab. For Cycles 2-17 chemotherapy will be scheduled on Days 1-2, Days 15-16, and Days 29-30 of each cycle. (NOTE: The exact days may be different for you.) You can receive FOLFIRINOX as directed by your doctor.

You will also have the following tests and procedures:

Prior to treatment on Cycle 1 (after PDT)

- Research imaging of your cancer with CT after PDT and prior to pembrolizumab
- Research blood samples (about 50 mL or about 3.5 tablespoons)



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- Research biopsy of lymph nodes if you are willing and the doctor thinks you will be a good candidate

End of Every Cycle (prior to starting the next cycle)

- Medical history and physical exam
- Routine blood testing
- Questionnaire
- Research blood samples (about 50 mL or about 3.5 tablespoons)

End of Every Other Cycle (end of Cycle 2, 4, 6, etc.)

- Routine imaging of your cancer

End of Treatment

- Medical history and physical exam
- Routine imaging of your cancer
- Routine blood testing
- Questionnaire
- Research blood samples (about 50 mL or about 3.5 tablespoons)

Safety Follow-up Visits (about 30 days after your dose of study treatment and about 90 days after your last dose of pembrolizumab) – we will contact you at a clinic appointment, or by telephone, or virtual visit to see how you are doing.

After all the visits above are complete, we will check on your health about every 3 months for up to 3 years. We will do this by telephone call, portal message, email, or at the time of a visit to Mayo Clinic.

If there are new findings about the treatments on this study that may affect your willingness to participate in this study, we will let you know.

Below is a table that lays out the plan for this study in a different way in case it is easier to understand.

Day	What will happen
Pre-Study Screening	• Medical history and physical exam including performance status, height, and weight • Routine blood testing including tests for your cancer • Routine imaging of your cancer • Pregnancy test if you are able to become pregnant



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Day	What will happen
On day of EUS/PDT	• Check into Clinical Research and Trials Unit (CRTU) prior to procedure NOTE: You will need to stay in the CRTU for a couple days after the PDT due to light sensitivity. • Research blood samples • Research biopsy during the PDT procedure
Before starting treatment with pembrolizumab (and FOLFIRINOX)	• Medical history and physical exam • Research imaging with CT scan on Day 2 after PDT and before pembrolizumab • Routine blood testing • Questionnaire • Research blood samples (about 50 mL or about 3.5 tablespoons)
Cycle 1 Day 3	• Routine blood testing • Research blood samples (about 10 mL or about 2 teaspoons)
At the End of Every Cycle	• Medical history and physical exam • Routine blood testing • Patient questionnaires • Research blood samples (about 50 mL or about 3.5 tablespoons)
At the End of Every Other Cycle (end of Cycles 2, 4, 6, etc.)	• Routine imaging of your cancer
End of Treatment	• Medical history and physical exam • Routine imaging of your cancer • Routine blood testing • Patient questionnaires • Research blood samples (about 50 mL or about 3.5 tablespoons)
Safety Follow-up Visits – about 30 days and about 90 days after your last dose of study drug	• Clinic visit, virtual visit, or phone call to see how you are doing

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or



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refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

Clinically relevant research results will be placed in your medical record.

Special Considerations:

Because we need to understand how verteporfin affects therapy, we are offering a substudy for a few patients. For this substudy, we would like to obtain another lymph node biopsy after the first dose of pembrolizumab and before starting chemotherapy with FOLFIRINOX (Cycle 1, Day 2-3). We would also like to obtain a PET-MRI about 3-4 months after photodynamic therapy (PDT). These tests and procedures are done for research purposes only and you would not have to pay for them.

Please read the following statement and mark your choice:

1. I am willing to take part in the substudy and have an additional biopsy and a PET/MRI. I understand that I will not have to pay for these procedures:

☐ Yes ☐ No Please initial here: _____ Date: _____

What are the possible risks or discomforts from being in this research study?

There are risks associated with the procedures and the drugs administered in this study.

Risks and effects of verteporfin

Common side effects (seen in more than 10% of patients)

- Discomfort or pain at the injection site
- Rash near or around the injection site

Less common side effects (more than 1% but less than 10% of patients)

- Fast and irregular heart rhythm (atrial fibrillation)
- Increased blood pressure (hypertension)
- Problems with blood circulation in your arms and legs (peripheral vascular disease, varicose veins)
- Skin irritation or rash including dermatitis and eczema
- Sensitivity to light (photosensitivity)
- Decreased blood level of albumin that may be a sign of damage to your kidneys



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- Difficult bowel movements (constipation)
- Feeling sick to your stomach (nausea)
- Inflammation or swelling of the prostate (prostatitis)
- Decrease in red blood cells (anemia) which may cause shortness of breath and tiredness
- Decrease in white blood cells (neutropenia) which may lower your ability to fight infections
- Increased white blood cells (leukocytosis), which can be a sign of infection
- Increased blood level of liver enzymes as seen on blood tests (AST, ALT) that measure how well the liver is working-- may be a sign of liver damage
- Numbness or tingling in any part of your body
- Muscle weakness (myasthenia)
- Trouble sleeping (insomnia)
- Dizziness
- Joint pain or disease (asthenia and arthropathy)
- Back pain
- Dry and itchy eyes (xerophthalmia)
- Inflammation of the eyelids (blepharitis)
- Cloudy lens that can cause decreased or distorted vision (cataracts)
- Pink eye or inflammation of the membrane of your eyes (conjunctivitis)
- Double vision (diplopia)
- Severe vision loss (blindness)
- Hearing loss
- Increased blood level of creatinine that may be a sign of damage to your kidneys
- Cough
- Fever
- Sore throat (pharyngitis)
- Stomach cancer
- Infection in the lungs (pneumonia)

Additional side effects reported after verteporfin became available on the market include chest pain, fainting from low blood pressure and low heart rate (vasopressor syncope), severe allergic reaction (anaphylaxis), muscular and joint pain during infusion, decreased vision and appearance of floating dark spots (floaters) (retinal detachment), decrease in outer visual field (retinal ischemia), decrease in central visual field (retinal pigment epithelium tear).

Pembrolizumab

Pembrolizumab, which is approved in the USA and some other countries, is available by prescription to treat many cancers but may not be approved to treat your type of cancer.



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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 these organs work, which can result in side effects. These side effects may be serious (i.e., causing hospitalization or be life-threatening), may result in death, and/or may occur after you stop taking pembrolizumab. These side effects can affect more than one of your normal organs and tissues at the same time.

VERY COMMON risks and side effects - Out of 100 people who receive pembrolizumab, 20 or more people may have the following:

- Itching of the skin
- Loose or watery stools (diarrhea)
- Cough

COMMON risks and side effects - Out of 100 people who receive pembrolizumab, at least 5 people but fewer than 20 people may have the following:

- Joint pain
- Rash
- Fever
- Back pain
- Pain in your belly
- Loss of skin color (vitiligo) – may lead to patchy appearance of the skin
- Not enough thyroid hormone – you may feel tired, gain weight, feel cold, or have infrequent or hard stools (hypothyroidism)
- Low levels of salt in the blood that may cause you to feel tired, feel confused, have a headache, have muscle cramps, or feel sick to your stomach (hyponatremia)

UNCOMMON risks – Out of 100 people who receive pembrolizumab, at least 1 but fewer than 5 people may have the following:

- Inflammation of the lungs, so you may feel short of breath and cough (pneumonitis)
- Too much thyroid hormone, so you may feel anxious, feel angry, have trouble sleeping, feel weak, tremble, sweat, feel tired, have loose and watery stools (hyperthyroidism)
- Infusion reaction, where you may feel dizzy or faint, feel flushed, get a rash, have a fever, feel short of breath, have a drop in your blood pressure while receiving your infusion or just after the infusion is done, or have pain at the site of the infusion
- Inflammation of the bowels or gut, which may cause severe pain in your belly with loose or watery stools, or black, tarry, sticky stools, or stools with blood or mucus (colitis)



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- Inflammation of the skin so you may have 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. (Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN))

RARE risks - Out of 100 people who receive pembrolizumab, less than 1 person may have the following:

- Inflammation of the sheath that covers the nerves (Guillain-Barré syndrome) that 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, so you may feel weak or have pain in your muscles (myositis)
- Inflammation of the pancreas (a gland in your abdomen that controls blood sugar levels), so you may have severe pain in the top part of your belly that may move to your back, feel sick to your stomach, and/or have vomiting that gets worse when you eat (pancreatitis)
- Inflammation of the eye, so you may have eye redness, blurred vision, sensitivity to light, eye pain, see floaters, or have headaches (uveitis)
- Inflammation of the liver that may make you feel sick to your stomach and vomit, not feel like eating, feel tired, have a mild fever, have pain in the right side of your belly, have yellow eyes and skin, and dark urine (hepatitis)
- Inflammation of the pituitary gland (a gland in the head), which may cause you to 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 (hypophysitis)
- Adrenal glands (glands on top of the kidneys) may not make enough hormone, which could cause tiredness, weight loss, muscle weakness, feeling faint, having joint, muscle, or belly aches; nausea, vomiting, loose or watery stools, fever, salt craving, and sometimes darkening of the skin like a suntan (adrenal insufficiency)
- Type 1 diabetes, a condition that can cause too much sugar in your blood – you may feel thirstier than usual, have frequent urination, and weight loss. If this type of diabetes occurs you are likely to need regular insulin shots
- Inflammation of the kidney, so you may pass less urine or have cloudy or bloody urine, swelling, and low back pain (nephritis)



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- Inflammation of the middle layer of your heart wall that may cause your heart to have difficulty pumping blood throughout your body, which can cause chest pain, shortness of breath, and swelling of the legs. You may experience a fast or irregular heartbeat that may cause dizziness or fainting (myocarditis)
- 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 the rate at which food is converted into energy (thyroiditis)
- A condition that may make you feel weak and tired and may cause 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)
- The formation of small clusters of immune cells (called granulomas) in parts of your body such as your lymph nodes, eyes, skin, or lungs (sarcoidosis)
- Inflammation of the brain with confusion and fever which may also include disorientation, memory problems, seizures (fits), changes in personality and behavior, difficulty speaking, headache, weakness, or loss of movement in some parts of your body, and loss of consciousness (encephalitis)
- Inflammation of the spinal cord with pain, numbness, tingling, or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating, or constipation (myelitis)
- Inflammation of the blood vessels - symptoms will depend on which blood vessels 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 have fever, weight loss, and fatigue (vasculitis)
- Low levels of parathyroid hormone (a hormone made by four tiny glands in your neck) which may result in low blood calcium and cause muscle cramps or spasms; fatigue or weakness; numbness, tingling, or burning in your fingertips, toes, or lips (hypoparathyroidism)
- Inflammation of the stomach - may have pain in your belly, feel full, or sick to your stomach; and may also have nausea, vomiting, or loss of appetite. (gastritis)
- Low number of red blood cells (cells that carry oxygen) due to destruction of red blood cells - may feel weak, tired, lightheaded, short of breath, or have a fast heartbeat; and may also have difficulty with physical exercise, pale or yellow skin, dark urine, or fever. (hemolytic anemia)
- Not enough pancreatic enzymes (proteins that break down food) that leads to poor digestion of food - may have bloating, gas, discomfort in your belly, diarrhea, abnormal stool that is oily, or weight loss (exocrine pancreatic insufficiency).



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- 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 the 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 which 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 scarring 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)

Pregnancy

If you can become pregnant you will be asked to have a pregnancy test before starting this study. If the test is positive, you will not be allowed to take part in this study. You must use birth control while on this study. Talk to your doctor about which birth control methods are appropriate.

If you miss a period or think you might be pregnant during the study, you must tell your study doctor immediately. The study doctor may ask for your permission to collect information about the outcome of the pregnancy and newborn child.



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Verteporfin Infusion and Photodynamic Therapy (PDT)

The major side effect of photodynamic therapy (PDT) with a verteporfin infusion is sensitivity to light. All patients who receive PDT will be sensitive to light for two to three days after the procedure. Patients must observe precautions to avoid exposure of the eyes and skin to direct sunlight for at least two days. Patients who receive verteporfin can be safely exposed to sunlight two days after sensitization. Some parts of your body may be more light-sensitive than others.

Before going outside, you should test a small area of skin in the light for 10 minutes to make sure the effects of the drug have worn off. If you don't swell, get a rash or blisters within 24 hours, you can gradually resume normal outdoor activities, initially continuing to exercise caution and gradually allowing increased exposure. If a reaction occurs with the limited skin test, you should continue the existing precautions for another week before re-testing. Since the face is very sensitive, it is not recommended as a safe testing area. If you travel to a different geographical area with greater sunshine, you should retest your skin.

Sunscreen will not help prevent side effects, because visible light, not UV, causes them. For three days following treatment, you should wear dark sunglasses when outdoors, and should consult your ophthalmologist if they notice any change in vision after treatment. You will be given information on barrier protection (hat, gloves, long sleeves etc) and an emergency contact number will be given.

In addition to photosensitivity, you may experience a change in blood pressure due to the infusion. Abnormalities in blood tests related to the liver have been noted in up to 10% of patients receiving the study agent. Other potential side effects although rare include pain, redness, swelling, or discoloration at the site of the injection, back pain during the infusion, dry eye, itchy eye, dry, itchy skin, constipation, nausea, muscle pain or weakness, decreased sensitivity to touch, or decreased hearing.

You will be monitored closely during and after the drug administration by the providing physician and study staff to ensure your safety.

Endoscopy with ultrasound

The risks of participating in this study are those that typically occur any endoscopic procedure using local anesthesia with sedation (allergic reaction to medications used, bruising or pain at the intravenous access site, hypoventilation) and the passing of an endoscope through the esophagus (difficulty or pain with swallowing, strictures in the throat, sore throat). The endoscopy itself may cause a cramping sensation in the stomach and you may feel bloated during the procedure because of air introduced into the stomach. The procedure is considered very safe, but it is possible to cause either bleeding or even a tear in the esophagus or stomach in rare (less than 1 in



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1000) cases. Inflammation of the pancreas (pancreatitis) is a possible rare complication which may require hospitalization for observation.

Ultrasound will be performed during the endoscopy to guide the scope and procedures. Ultrasound creates images of the pancreas and other internal organs by sending out sound waves. Because the sound waves don't need to pass through the skin and muscle to reach internal organs, endoscopic ultrasound offers a better view of the GI tract and nearby organs than abdominal ultrasound. You may feel some pressure as the ultrasound is moved around.

Radiation Risk

You will be exposed to radiation if CT is used to perform the biopsy. You will also be exposed to radiation for the research CT performed after the PDT procedure. The amount of radiation has a low risk of harmful effects.

If you can become pregnant, you must have a pregnancy test prior to the CT or biopsy using CT.

Biopsies

Biopsies are normally performed under the guidance of an imaging technique, such as ultrasound or CT. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort -The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site
- Tenderness at the biopsy site
- Scarring at the biopsy site
- Rarely, an infection at the biopsy site

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Blood draws

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Standard of care risks

Your doctor will discuss the risks of these tests and procedures, which are part of regular care for your cancer:

- Treatment with FOLFIRINOX
- Imaging of your cancer (CT, PET/CT, PET/MRI, etc.)



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Confidentiality risk

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Unforeseeable risks

Many side effects go away shortly after the study drugs are stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death. Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell your study doctor if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety.

In addition, the study doctor or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped,
- For administrative reasons, including competitive enrollment.

If any new information becomes available that may be relevant to your willingness to continue participation in this research study, the study team will inform you in a timely manner.

If you choose to withdraw from this clinical trial, your original consent to data or sample processing is still valid. Any results obtained from testing of your samples can still be used by Mayo Clinic. However, no other new samples will be collected, and you may also request that no new analyses be performed after withdrawal. If you decide at any time during the period of the trial that you want any of your submitted samples withdrawn, you will need to contact your study doctor in writing, who will then contact the laboratory to have your samples destroyed. However, any results already obtained from testing of your samples can still be used.



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What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments, and coinsurance. The study will not offer free medical care or payment for any bad side effects from taking part in this study.

What are the possible benefits from being in this research study?

This study may not make your health better. However, others with pancreatic cancers may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include treatment for your cancer without being on a study, treatment on a different research study, or no treatment. Talk to the Principal Investigator or your doctor if you have any questions about any of these alternative treatments or procedures.



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What tests or procedures will you need to pay for if you take part in this research study?

The study drugs, verteporfin and pembrolizumab, will be provided to you while you are in this study. You will not need to pay for them.

You will not need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Your stay in the Clinical Research and Trials Unit (CRTU) at Mayo Clinic Hospital
- Endoscopic ultrasound (EUS)
- Photodynamic therapy (PDT)
- Research CT scan after PDT (Day 2-3)
- Research biopsies
- Research blood tests and research testing on your blood
- Research testing on tumor tissue
- Research imaging with PET-MRI, if taking part in the substudy

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular medical care. These tests and procedures include:

- Routine exams, blood testing including pregnancy testing (if needed), and imaging scans as needed
- Other drugs or treatments which are given to help you control side effects
- FOLFIRINOX and its administration

Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance.

If you have billing or insurance questions, call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

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



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There is a very small chance that some commercial value may result from the use of your donated samples. This could include new products like a drug or a test to diagnose a disease. If that happens, you won't be offered a share in any profits.

Will your information or samples be used for future research?

Your information and samples will be kept by the Sponsor, Mayo Clinic. Mayo Clinic can use your data and samples for research purposes only as described in the research study. Your data and samples will be kept by Mayo Clinic in a coded format, which protects your identity. Mayo Clinic may destroy the samples at any time without telling you. We will test your tissue and blood as part of this study. In addition, we would like to keep your study information and samples for future research. You can still take part in this study without giving permission to use your data and samples for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. Your sample will be sent to researchers in a coded format, which protects your identity. Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that re-identified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.



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Please read the following statements and mark your choices:

2. I permit my information and samples to be stored and used in future research to learn about, prevent, or treat cancer:

☐ Yes ☐ No Please initial here: _____ Date: _____

3. I permit my information and samples to be stored and used in future research to learn about, prevent, or treat any other health problems (for example, causes of diabetes, heart disease, and Alzheimer's, or genetic links to alcoholism):

☐ Yes ☐ No Please initial here: _____ Date: _____

4. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____ Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved. Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

It is possible that information identifying your samples, or your data could be removed. These samples and data will no longer be linked to you. If that were to happen, the samples and data could be used for future research studies or given to another researcher without asking for your permission.

How will your privacy and the confidentiality of your records be protected?

General Protections

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All of your research samples transferred to the Mayo Clinic or designee will be labeled with a code number and kept in locked storage. Only your study doctor will be able to link your samples with your identity. No one working with your samples



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will know your identity. If the results of the research are made public, information that identifies you will not be used.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Authorization to Use and Disclose Protected Health Information (HIPAA)

During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or “authorization”) to Mayo Clinic.

Your health information may be collected from:

- Past, present, and future medical records.
- Research procedures, including research office visits, tests, interviews, and questionnaires.



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Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Other healthcare providers involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study, Mayo Clinic, and the people or groups hired by Mayo Clinic to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports, or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic, or other methods), or remove your identifying information from Mayo Clinic.



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Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

Genetic Information Nondiscrimination Act (GINA)

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

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

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.



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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 First St. SW
Plummer Building PL 3-02
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.



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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)
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Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)
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Signature