

MC210601 / 21-012233

Phase II Clinical Trial Of PLX038 In Patients With Platinum-resistant Ovarian, Primary Peritoneal And Fallopian Tube Cancer

NCT05465941

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC210601 Phase II Clinical Trial of PLX038 in Patients with Platinum-resistant Ovarian, Primary Peritoneal, and Fallopian Tube Cancer

IRB#: 21-012233

Principal Investigator: Andrea E. Wahner Hendrickson, M.D., Scott H. Kaufmann, M.D., Ph.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 PLX038 is safe and effective for treating ovarian cancers. (Ovarian cancers include primary peritoneal and fallopian tube cancers.) You are being asked to take part in this research because you have been diagnosed with an ovarian cancer that has recurred.
What's Involved	Study participation involves about the same amount of time as regular care for your cancer. Procedures include receiving treatment with PLX038 through a vein in your hand or arm or through a port if you have one. PLX038 is given once every 3 weeks.



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	You will be asked to have blood drawn for research purposes. We will draw the research blood at the same time as blood draws for your clinical care. These blood draws will be prior to any treatment, the day after your first treatment, and one week after your first treatment, and any time you are having diarrhea. You will be asked to have two biopsies for research – one just before you start treatment and the other a week after your first treatment. You will be asked to provide stool samples for research at baseline, one week (Day 8), and three weeks after starting treatment (end of Cycle 1), and any time you are having diarrhea. You will receive treatment with PLX038 as long as your cancer is not getting worse, and the side effects are tolerable. After you finish treatment with PLX038 we will follow your health for up to 5 years.
Key Information	The risks associated with study participation are completely described later in this form and may include the potential for life-threatening side effects from treatment. Be sure to review the risks carefully. 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 carefully. 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.



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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 Investigators: Dr. Andrea Wahner-Hendrickson Dr. Scott Kaufmann 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.

A description of this research study will be 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 because you have been diagnosed with an ovarian cancer that has “metastasized” or spread to other parts of your body.

The plan is to have up to 43 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 PLX038 and whether PLC038 is effective in treating recurrent ovarian cancer.

PLX038 is “investigational.” Investigational means that the U.S. Food and Drug Administration (FDA) has not approved the PLX038 for treatment of ovarian cancers, although they are allowing it to be used in this study.

Information you should know

Who is Funding the Study?

This study is being funded by the Mayo Clinic Ovarian Cancer Research Program, which is a group of physicians and scientists who are performing research to improve the prevention, detection, and treatment of ovarian cancer. The Ovarian Cancer Research Program receives funding from the Federal government, private foundations, and the Mayo Clinic.

The pharmaceutical company, ProLynx Inc., which has developed PLX038, will pay Mayo Clinic to cover the costs of running 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.



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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.

This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.

Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research, and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.

One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

You may receive treatment in this research study until your cancer 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 the patient portal.

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

If you agree to take part in this clinical research study, you will be asked to first sign this informed consent form. If you decide to participate in the study, some tests will be done to see if you are eligible.



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If the test results show that you do not meet study requirements, you will not be able to start the study. The study doctor will discuss other options with you and/or refer you back to your regular doctor.

You will be asked questions about your medical history and medications you are currently taking. For your own safety, it is important that you be thorough and honest with this information. The screening visit will take several hours. You will need to have the following examinations, tests, or procedures to find out if you can be in the study. Most of these examinations are part of regular cancer care. If you have had some of them recently, they may not need to be repeated. Your study doctor will decide which tests need to be repeated.

Before starting this study, you will need to have the following tests to see if you are eligible:

- Medical history - we will ask basic questions (age, gender, race), and about your prior surgeries, prior and ongoing medical illnesses, and prior treatments for your disease
- Physical exam including measurements of your vital signs (pulse, blood pressure, temperature), and your height and weight
- ECOG Performance Score: We ask you to rate on a scale how you feel performing normal everyday actions
- Electrocardiogram (ECG): ECGs measure the electrical activity of the heart. This measurement is an indication of the overall health of your heart.
- Routine blood tests including complete blood count, blood chemistry, and coagulation; and CA-125 measurement
- Routine imaging of your tumors to determine their size and location before starting the study (usual imaging methods may include CT, PET/CT, MRI, ultrasound, or X-ray)
- Pregnancy testing if you are able to become pregnant

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 study doctor.

If you agree to be in this study and sign this consent form, you may have the following tests and procedures. These tests are done for research purposes, and you will not have to pay for them.

- Blood draw for research testing (30 ml or about 2 tablespoons)
- Stool sample for research testing on microbiome – a kit will be provided to you, which you will need to complete and return either by dropping it off at Mayo Clinic or dropping it off at a Federal Express location for overnight shipping.



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- UGT1A1 testing - A blood sample will be collected for a genetic test (performed in a lab) to study a specific gene that is needed to metabolize (breakdown) the study drug. There is a possibility you will not be eligible to participate in this study, based on the results of this UGT1A1 test.
- Biopsy of your cancer

All patients will receive PLX038, an investigational drug that is poisonous to cancer cells. PLX038 is able to stay in the body longer than other chemotherapy drugs. By staying longer, it may have more of an effect on cancer.

You will receive PLX038 by IV on Day 1 of every 21-day cycle.

For the first cycle only, you will have a research blood draw (20 ml or about 1.5 tablespoons) immediately after the infusion on Day 1 and again on Day 2 (24 hours after your first dose of PLX038).

You will have a research biopsy around Day 8. This biopsy is required; however, you will not have to pay for it. In addition, you will be asked to complete a research stool collection kit.

For the first two cycles you will need to come back to the clinic every week on Days 8 and 15 for blood tests to make sure you are doing all right. For Cycle 1 only, we will collect research blood (20 ml or about 1.5 tablespoons) at the same time.

At the end of the first cycle (just before Cycle 2), we will ask you to provide another blood sample (20 ml or about 1.5 tablespoons) and complete another research stool collection kit.

If you have diarrhea or loose stools at any time, we may ask you to provide a stool sample and a blood sample (20ml or about 1.5 tablespoons) for research testing, to help us understand why some people get diarrhea and others do not.

Starting with the third cycle, you will only need to come to the clinic once every three weeks.

After every third cycle (end of Cycles 3, 6, 9, etc.) you will have routine imaging to see how your cancer is doing.



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Here is a table of what will happen and when:

When	What will happen
Screening	• Medical history and physical exam • Electrocardiogram (ECG) to measure the electrical activity of the heart • Routine blood tests including CA-125 • Routine imaging of your cancer • Pregnancy testing if you are able to become pregnant • Research biopsy of your cancer • Research blood draw • Research stool sample • UGT1A1 testing on your blood
Cycle 1, Day 1	• Receive PLX038 into a vein in your arm or hand • Research blood draw
Cycle 1, Day 8	• Routine blood testing • Research blood draw • Research stool sample • Research biopsy of your cancer
Cycle 1, Day 15	• Routine blood testing • Research blood draw • Electrocardiogram (ECG) to measure the electrical activity of the heart
Prior to treatment on Cycle 2, Day 1	• Physical exam and vital signs • Electrocardiogram (ECG) to measure the electrical activity of the heart • Routine blood testing including CA-125 • Research blood draw • Research stool sample
Cycle 2, Day 1	• Receive PLX038 into a vein in your arm or hand
Cycle 2, Day 8, and Day 15	• Routine blood testing
Prior to every cycle starting with Cycle 3	• Physical exam and vital signs • Electrocardiogram (ECG) to measure the electrical activity of the heart • Routine blood testing including CA-125
End of every third cycle (end of Cycle 3, 6, 9, etc.)	• Routine imaging of your cancer



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When	What will happen
End of treatment visit	- Physical exam and vital signs - Electrocardiogram (ECG) to measure the electrical activity of the heart - Routine blood testing including CA-125

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

Risks and Side Effects from PLX038

Common risks:

As with most chemotherapies, PLX038 is expected to cause the following:

- Fewer white blood cells which can increase the risk of infection
- Fewer red blood cells (anemia) which can give you shortness of breath, weakness, and fatigue
- Fewer platelets (cells that allow your blood to clot when you bleed) which can cause easy bruising or bleeding
- Loose, frequent stools (diarrhea)
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Loss of appetite – not feeling hungry, not wanting to eat
- Weight loss

The effect on the bone marrow is usually temporary and some of these drops in blood cell counts can be helped with transfusions, if needed, until your body recovers. If you develop signs of infection, such as a fever, you may be given antibiotics and you may be hospitalized. You will be watched carefully for these side-effects.

If your doctor is concerned about unusual side-effects on your bone marrow, he or she may ask you to have a bone marrow test. This test is done under a local anesthetic. Your doctor would obtain a small sample of your bone marrow. The most common side-effect from this test is some pain at the site where the needle is introduced. This effect is normally treated with common pain medication like acetaminophen (Tylenol). Rarely, severe bleeding or infection may occur.

Potential side effects of PLX038, based on animal studies:

- Hair loss (alopecia)



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- Pigmentation (dark spots) of the cornea, the transparent front part of the eye, which may cause loss of vision. Small spots appeared in the eyes of some monkeys that were given PLX038. After stopping the drug, the spots went away in some, but not all, monkeys. A few monkeys that had normal eyes started to develop spots after stopping the drug.
- Liver damage

A rare but serious side-effect which may occur is an allergic reaction to the drug or one of the ingredients in the drug. An allergic reaction may include a rash, wheezing, shortness of breath, heart palpitations, swelling of the face and lowered blood pressure. Rarely, allergic reactions can be life threatening or can cause death. To help prevent an allergic reaction your study doctor may give you some medicines before each cycle of PLX038. If you do have an allergic reaction, you will receive immediate treatment for it. If you have a history of allergic reactions to similar drugs (for example, irinotecan), then being in this study is a risk for you and you should inform your study doctor of this before receiving any treatment.

Additional risk for patients who carry abnormal UGT1A1 gene

Patients who carry one copy of the abnormal allele (a particular variant of gene) UGT1A1*28 may have an increased incidence of adverse events, especially patients may experience a

decrease in the number of one type of white blood cells (neutrophils) because of receiving the study treatment. Your doctor will inform you of the results of your UGT1A1 blood test so that you are aware of whether you may have a greater risk of an adverse event.

Other risks and side effects

There may be additional risks or side effects that are unknown at this time.

Your condition may not get better or may become worse while you are in this study.

Certain drugs may increase the severity of these side effects if taken during the study. Ask your study doctor for a full list of prohibited medications.

Risks of tumor biopsy

During the study, we will perform a biopsy on two separate occasions to obtain samples from your tumor. This is considered a safe procedure that is commonly performed. Although serious complications are not expected to occur, they can be life-threatening in rare cases.

Biopsies are done with imaging to guide the needle placement. Most are done with ultrasound guidance or CT guidance. During a CT guided biopsy, X-rays are used to guide the needle placement.



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Before the procedure, a numbing medication may be applied to the tumor site. During the procedure you may experience some discomfort when the needle is inserted. After the procedure, you may have minor pain and/or swelling or soreness at the biopsy site that can be relieved by over-the-counter pain medications. Minor bruising and/or bleeding under the skin at the biopsy site may occur.

Blood Draw

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

Radiation Risk

If a biopsy is performed with CT guidance, you will be exposed to radiation. The amount of radiation has a low risk of harmful effects.

Confidentiality

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

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.

Genetic Testing/Whole Genome

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code).



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You will not be notified of the genetic test results, and they will not be put into your medical record.

Pregnancy Risks for Persons able to become Pregnant

The effect of chemotherapy on a fetus (developing baby still in the womb), or on a breastfeeding infant, may be harmful. Because of these risks, no one cannot take part in this study if they are pregnant or breastfeeding.

If you are able to become pregnant, you must have a negative pregnancy test in order to participate in this study.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Sexual abstinence
- Vasectomy
- Bilateral tubal ligation/occlusion
- Condom with spermicide (males) in combination with barrier methods (diaphragm, cervical cap, or cervical sponge), hormonal birth control or IUD (females)

And you must use birth control for the entire study and for at least 3 months after your last dose of PLX038.

Are there reasons you might leave this research study early?

The study doctor may stop you taking part in this study at any time. The study doctor will tell you if this happens. Some reasons this could happen include:

- Staying in the study could be harmful to you.
- You need treatment not allowed by the study.
- You are not able to complete the study procedures as required.
- You become pregnant.
- The study is stopped for reasons not related to you.

There may be other reasons to stop you taking part in this study that are not known at this time.

When you stop participating in this study, all information and samples collected from you before you stopped taking part in the study may still be used the study team.



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If you want to stop taking part in the study, you may still be asked to come back for some additional tests and procedures. The study doctor will discuss the following options with you:

- You can stop taking the study drug(s) but continue with all other study tests and procedures.
- You can stop the study but allow the study doctor to collect information about your health by reviewing your medical records, by contacting you, a family member, or a legal representative, or through other means as allowed by local law such as accessing public records.
- You can completely leave the study and have no more contact with the study doctor for study related procedures or questions as of the date of your request.

If you stop taking part in the study, or the study ends early, you will stop receiving the study drug(s).

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.

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

No one knows if taking part in this study will help you. Your condition may get better, but it could stay the same or even get worse. The information from this study might help in the development of additional treatments in the future for ovarian cancer.



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

You can choose not to take part in this study. If you do not wish to take part, the study doctor will discuss other healthcare choices with you.

Your other choices may include:

- Getting treatment for care for your cancer without being in a study.
- Taking part in another study.
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Discuss your choices with your doctor before you decide if you will take part in this study. If you decide not to participate in this study, your decision will not affect your medical care in any way.

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

You won't need to pay for tests and procedures that are done just for this research study. These tests and procedures are:

- Study drug, PLX038, and its administration
- CT or US guided biopsies prior to starting the study and about one week after your first treatment
- Research testing on blood, stool, and tissue

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- All physical exams
- Imaging of your cancer
- Routine blood or laboratory tests

You will also be responsible for any co-payments and deductibles. You and/or your insurance might also have to pay for other drugs or treatments given to help control side effects.



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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 won't be paid for taking part in this study.

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

Will your information or samples be used for future research?

We will collect and test your tissue and blood as part of this study. We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, 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.



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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 reidentified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Please read the following four statements and mark your choices:

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

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

2. I permit my information and samples to be stored and used in future research at Mayo Clinic 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) at Mayo Clinic:

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

3. I agree to have my coded genetic information and coded medical information placed in password-protected secured databases for research analyses.

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

4. I permit my information and samples to be shared with 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.



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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?

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

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, 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.

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.



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- Other Mayo Clinic staff involved in your clinical care.
- Mayo Clinic, the sponsor of this study and the people or groups hired by the sponsor 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.

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.



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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.

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
Plummer Building PL 3-02
200 1st Street SW
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