MC210504 / 21-013057

Phase II Trial of Pertuzumab, Trastuzumab, and Hyaluronidase-zzxf (HP) Plus Enzalutamide for the Treatment of Selected Patients With Metastatic Castration-Resistant Prostate Cancer (TraPPer)

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MAYO CLINIC

Name and Clinic Number
Protocol #: MC210504 **Version #: Main Study** **Version Date:14Jan2025**

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC210504 Phase II trial of Pertuzumab, Trastuzumab, and Hyaluronidase-zzxf (HP) plus Enzalutamide for the Treatment of Selected Patients with Metastatic Castration-Resistant Prostate Cancer (TraPPer)

IRB#: 21-013057

Principal Investigator: Jacob J. Orme, M.D., Ph.D., Sean S. Park, M.D., Ph.D., Brian A. Costello, M.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 a drug that contains pertuzumab, trastuzumab, and hyaluronidase (HP) used in combination with the standard anti-androgen drug, enzalutamide, has an effect on advanced prostate cancer. You have been asked to take part in this research because you have prostate cancer that has metastasized or spread to other parts of your body.
What's Involved	Study participation involves about the same amount of time as regular care for your cancer. The procedures are fully described later in this consent form, be sure to read them carefully.

	Prior to starting you will have a blood draw to see whether your tumors have the biomarker called NRG-1. If your tumors have NRG-1, and you complete the screening, you may receive treatment with a combination drug containing pertuzumab, trastuzumab, and hyaluronidase (HP) plus enzalutamide. You will receive HP by injection (a needle into your skin) once every 3 weeks (21 days), and you will take enzalutamide by mouth every day. You may continue to receive these drugs for up to one year as long as your cancer is not getting worse, and you are not having intolerable side effects. We will follow your health for up to two years after you start this study.
Key Information	The main risks from this study are from the drugs being used. The most common risks of pertuzumab, trastuzumab, hyaluronidase (HP) are loose or frequent stools (diarrhea), hair loss (alopecia), low number of a type of blood cells called neutrophils (neutropenia), feeling sick to your stomach (nausea), feeling very tired or weak (fatigue), rash, and numbness or tingling in your hands and feet (peripheral neuropathy). The most common risks of enzalutamide are feeling tired or weak (fatigue, asthenia), back pain, hot flush, hard stools (constipation), joint pain (arthralgia), not feeling hungry (decreased appetite), loose or frequent stools (diarrhea), and high blood pressure (hypertension). The risks of this study are fully described later in this document. Be sure to read them carefully. There are alternatives to taking part in this research. The research team will discuss the other treatment options with you. Some of the costs of the study are paid for by the research. Your insurance or you will be billed for enzalutamide. In addition, you will have to pay for other tests and treatments used to treat your cancer such as scans and blood tests.

	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.

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. Jacob Orme, Dr. Sean Park, and Dr. Brian Costello (MN) **Phone:** MN: (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)** **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.

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 prostate cancer that has metastasized (spread to your body) and there are limited treatment options for your disease.

Up to 8 people will take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this study is to see whether a drug that contains pertuzumab, trastuzumab, and hyaluronidase (HP) used in combination with the standard anti-androgen drug, enzalutamide, has an effect on advanced prostate gland cancer that is castration-resistant.

Pertuzumab, trastuzumab, and hyaluronidase (HP) in combination with enzalutamide is not approved by the U.S. Food and Drug Administration (FDA) for the treatment of advanced prostate gland cancer. However, the FDA has allowed the use of these drugs in this research study.

By enrolling in this study, you may have to forego other treatment options with proven survival benefit.

Information you should know

Who is Funding the Study?
The National Cancer Institute is providing funding to Mayo Clinic to run this study.
Genentech is providing pertuzumab, trastuzumab, hyaluronidase (PHESGO™) for use in 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.

How long will you be in this research study?

You will be in this study until your cancer gets worse ("progresses") or you have side effects that you cannot tolerate.

You may receive treatment with pertuzumab, trastuzumab, hyaluronidase (HP) for up to about 1 year (17 total doses).

After you stop treatment, we would like to keep track of your health for up to two years after you start the study. We will do this by reviewing your medical record, calling you, or sending you and email or a note in the patient portal.

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

Before you can take part in this study, you will need to sign this informed consent form and have the following tests and procedures:

- Blood sample for research

We will test a portion of your blood for a biomarker, called NRG-1. If you do not have this biomarker, you are not eligible for this study.

If you have the NRG-1 biomarker and you are eligible and willing to take part in this study, you will have the following:

- Medical history and physical exam including performance status (assessment of your activity level), height, weight, and vital signs (temperature, blood pressure)
- Routine blood testing including PSA
- Routine imaging of your cancer
- Echocardiogram (echo) to test your heart function
- Biopsy of your cancer for diagnostic and research purposes

These tests and procedures are part of regular care for your cancer. If you have had some of them recently, they may not need to be redone. That decision is up to the study doctor.
If you have not had a biopsy recently, you will need to have a biopsy to collect tissue for research. You will not have to pay for this biopsy.

In addition, we will collect blood samples (about 8.5 tablespoons) for research before you start treatment. We will try to schedule these samples at the same time as blood draws for your clinical care. And we will ask you to complete two questionnaires to tell us about any symptoms you are having and your quality of life.

Once you start the study, you will be treated in cycles. A treatment cycle for this study is defined as 21 days (about 3 weeks).

Pertuzumab, trastuzumab, hyaluronidase (HP) is given by subcutaneous injection into your thigh on Day 1 of every cycle. The first dose is over about 8 minutes on Cycle 1, Day 1, and you will need to be observed for about half an hour. Starting with Cycle 2, Day 1 the doses are given over 5 minutes, and you only need to be observed for about 15 minutes.

Enzalutamide comes in capsules or tablets you take by mouth with water. You should take it one time per day at about the same time every day. If you miss a dose, take it as soon as you remember it. If you miss an entire day, skip that dose, and start with your next dose.

You will be given a diary to record when you take enzalutamide. You will need to return to Mayo Clinic every three weeks for a re-evaluation before starting your next cycle of treatment. You will be asked to bring your diary, pill bottle(s) including any that are empty, and any remaining tablets at the end of each cycle.

You will have the following tests and procedures prior to every cycle:

- Medical history and physical exam including performance status, weight, and vital signs (temperature, blood pressure)
- Routine blood testing

You will have the following tests and procedures every 9 weeks for 27 weeks, then every 12 weeks

- Routine imaging of your cancer
- Echocardiogram to check your heart function
- Routine blood samples with additional blood taken for research (about 2 tablespoons)
- Complete two questionnaires
- Biopsy of your cancer when you stop study treatment

Observation
Once you finish treatment with pertuzumab, trastuzumab, hyaluronidase (HP) and enzalutamide, you will enter observation. During this phase you will return to be seen in the clinic every 3 months for up to 1 years after you started the study. You will have exams, blood testing, and imaging to see how your cancer is doing.

Below is a table that shows what will happen and when.

Table of Events

Timing	What will happen
Pre-Study	• Routine tests and exams • Routine imaging of your cancer • Routine blood testing including PSA • Research testing of your blood for NRG-1
Prior to starting treatment	• Routine tests and exams including echocardiogram (Echo) • Research blood samples (about 8 ½ tablespoons) • Biopsy of your cancer (or archival tissue submission) • Complete two questionnaires
Cycle 1, Day 1	• Receive pertuzumab, trastuzumab, hyaluronidase (HP) by subcutaneous injection into your skin over about 8 minutes • Start taking enzalutamide once per day
Cycle 1, Days 2-21	• Continue taking enzalutamide every day
Prior to treatment on Cycle 2 and beyond	• Routine tests and exams • Routine blood testing including PSA • Research biopsy if you are willing • Bring your diary and your pill bottles to your appointment
Cycles 2 and up, Day 1	• Receive HP by subcutaneous injection over about 5 minutes • Continue taking enzalutamide once per day
Every 9 weeks for 27 weeks (Week 9,18,27), then every 12 weeks (Week 29,51, etc.), and end of treatment	• Routine imaging of your cancer • Echocardiogram (echo) • Complete two questionnaires • Biopsy at end of treatment if you stop treatment for any reason • Routine blood testing
After you finish treatment – every 3 months for one year	• Routine tests and exams • Routine blood testing including PSA • Routine imaging of your cancer

If there are new findings about pertuzumab, trastuzumab, hyaluronidase (HP) or enzalutamide that may affect your willingness to participate in this study, we will let you know.

If you have a tumor tissue biopsy at any time during this study as part of your clinical care and there is tumor tissue that is not needed for your clinical care, a portion of this tissue will be requested for research on this study.

Special Considerations
Because we need to understand how the treatment affects the cancer and your body, we would like to obtain a tissue sample for research purposes after you have received some treatment or if your cancer comes back (recurrence).

We would like to perform a research biopsy to obtain tissue after you have completed one cycle of treatment. You would not have to pay for this biopsy.

If your cancer comes back and you have another biopsy or surgery as part of your treatment, we would like to request a portion of that tissue. You will not need a new biopsy to obtain this tissue.

Please read the following <u>two</u> statements and mark your choices:

1. I am willing to have a biopsy to obtain tissue for research after 1 cycle. I understand I will not have to pay for this biopsy:

☐ Yes ☐ No Please initial here: _____Date: _____

2. If my cancer comes back and I have a biopsy or surgery as part of diagnosis and treatment, I permit Mayo Clinic to obtain a tissue sample from that biopsy or surgery. I understand I will not need another biopsy or surgery to obtain this tissue.

☐ Yes ☐ No Please initial here: _____Date: _____

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

Risks and side effects of pertuzumab, trastuzumab, hyaluronidase (PHESGO)

Very common risks and side effects occurring in greater than 20% of people taking HP

- Hair loss (alopecia)
- Feeling sick to your stomach (nausea) or throwing up (vomiting)
- Frequent or loose stools (diarrhea)
- Hard stools (constipation)
- Sores in the mouth and throat (stomatitis)
- Low number of red blood cells (anemia) may make you feel tired or weak
- Low number of neutrophils (neutropenia)
- Feeling weak (asthenia)
- Feeling tired (fatigue)
- Muscle pain (myalgia)
- Joint pain (arthralgia)

Common risks and side effects occurring in 10-20% of people

- Swelling, pain, and redness in lining of mouth, nose, throat, stomach, intestines, bladder (mucosal inflammation)
- Swelling and pain at the injection site (injection site reaction)
- Fever (pyrexia)
- Altered tastes (dysgeusia)
- Numbness and tingling in hands and feet (peripheral sensory neuropathy, peripheral neuropathy, paresthesia)
- Headache
- Dizziness
- Weight loss
- Back pain
- Cough
- Nosebleed (epistaxis)
- Trouble breathing (dyspnea)
- Upper respiratory tract infection
- Not feeling hungry (decreased appetite)
- Trouble sleeping (insomnia)
- Hot flush

Rare, serious side effects occurring in less than 5% of people

- Change in heart function (left ventricular ejection fraction decreased) – this effect is usually reversed once patients stop taking the drug
- Itching (pruritus)

The following reactions have been reported among patients receiving FDA-approved versions of pertuzumab and trastuzumab, although frequency and relationship to the study drugs is unknown:

- Kidney damage (glomerulopathy)
- Low platelet count (immune thrombocytopenia)
- Tumor lysis syndrome (TLS) which may appear as kidney damage (hyperuricemia, hyperphosphatemia) or kidney failure (renal failure)

Risks and side effects of enzalutamide

Very common risks and side effects occurring in greater than 20% of people

- Feeling very tired (fatigue)
- Frequent or loose stools (diarrhea)
- Hot flashes
- Pain in muscles or bones (myalgia, arthralgia)

Common risks and side effects occurring in 4-20% of people

- Headache
- Trouble falling asleep or staying asleep (insomnia)
- Feeling nervous or fearful (anxiety)
- Low white blood cell (WBC) count which may lead to infection
- Abnormal blood test of liver function (AST, ALT, bilirubin)
- High blood pressure (hypertension)
- Falls due to muscle weakness or dizziness
- Dry or itchy skin (pruritus)
- Thinking or memory problems

Rare, serious side effects occurring in less than 3% of people

- Brain disorder characterized by headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome or RPLS)
- Seizures
- Seeing, feeling, or hearing things that are not there (hallucinations)
- Lack of blood supply to the heart due to blocked blood vessels (ischemic heart disease)

Other Risks and Side Effects Due to Study Participation

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

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

- Discomfort or pain. The amount of 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.

Some biopsy procedures require imaging studies, such as a CT scan or ultrasound to plan or guide the procedure. These studies would be done even if you were not donating samples for research purposes. However, if the biopsy is done for research, the imaging studies would also be considered research. Your doctor will tell you whether imaging studies are required for your procedure.

If you have a CT scan, there is also a small risk of allergic reaction to the dye that may be used during the scan. You could have anxiety or claustrophobia in the scanning machine. Talk to your doctor if you have had problems during a CT scan in the past.

Radiation risk from biopsies
As part of the study, you may have up to two CT-guided biopsies. The CT-guided biopsy procedure requires exposure to radiation. The amount of radiation you will receive has a low risk of harmful effects.

Echocardiogram
This test uses sound waves to look at your heart. The person doing the test will press on your chest with a machine to obtain the pictures. The pressure may be uncomfortable.

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.

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

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator 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 Principal Investigator 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.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

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?

This study may not make your health better, although we are hopeful that the methods used in this study may be a more effective way to treat your cancer. It is hoped that the information learned from your participation in this study may help other patients with cancer in the future.

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: Current options include other chemotherapy
- Treatment on a different research study
- No treatment

Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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

The study drug: pertuzumab, trastuzumab, hyaluronidase (HP or PHESGO) will be provided by Genentech, Inc. You will not need to pay for it.

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

- Research biopsy when you stop treatment or End of Cycle 6 (whichever comes first)
- Research blood tests and research testing on your blood
- Research testing on tumor tissue

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

- Enzalutamide (XTANDI)
- Routine exams, blood tests, biopsies, and imaging scans as needed
- Other drugs or treatments which are given to help you control side effects

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 being in this study.

There is a very small chance that some commercial value may result from the use of your donated samples. If that happens, you won't be offered a share in any profits.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

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.

GINA
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.

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.

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.

Please read the following <u>three</u> 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:

☐ Yes ☐ No Please initial here: _____Date: _____

2. 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: _____

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: _____

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?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

All of your research samples given to Mayo Clinic will be labeled with a code number and kept in locked storage. Only your study team 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.
- Other Mayo Clinic staff involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) 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.

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.

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)

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)

Signature