MC1266 / 12-007859

Phase I/II Trial of Intraperitoneal Administration of Adipose Tissue Derived Mesenchymal Stem Cells Infected with a NIS-Expressing Derivative Manufactured from a Genetically Engineered Strain of Measles Virus in Patients with Recurrent Ovarian Cancer

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MAYO CLINIC

Name and Clinic Number
Protocol #: MC1266 **Version #: MCCC Addendum 12 – Main Consent** **Version Date:22Mar2024**

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: "MC1266 Phase I/II Trial of Intraperitoneal Administration of adipose tissue derived mesenchymal stem cells infected with a NIS-Expressing Derivative Manufactured from a Genetically Engineered Strain of Measles Virus in Patients with Recurrent Ovarian Cancer"

IRB#: 12-007859

Principal Investigator: Evanthia Galanis, M.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. E. Galanis	**Phone:** (507) 285-2411 **Address:** Mayo Clinic 200 1st St SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate (The RPA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** ResearchParticipantAdvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

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.

1. 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 recurrent ovarian cancer that has progressed on chemotherapy. This study is being done to test the safety of an engineered strain of the measles virus as well as derived fat tissue stem cells infected with the virus and to see what effects (good and bad) it has on you and your disease.

The plan is to have about 36 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The idea of using measles virus strains as anticancer therapy has emerged from the observation that natural measles infection may result in an antitumor effect (cancer fighter).

This study is being done:

- to learn the highest dose of stem cells infected with modified measles virus that can be given in the abdominal cavity of patients with recurrent ovarian cancer by using escalating doses of the cells in consecutive groups of patients without causing unacceptable side effects;
- to look at the side effects of the virus when administered in the abdominal cavity; and,
- to assess the virus' effects in the body using blood, urine, throat gargle specimen(s), and tissue samples.
- to see how effective the use of your own cells as a viral delivery vehicle is. Current methods have potential limitation of the virus being partially neutralized by antibodies and therefore less effective against your cancer. Also with current methods, there is only a limited time of contact with the tumor sites of 4-6 hours which also potentially reduces virus effectiveness.
- to determine how well your stem cells accept being infected with the measles virus

3. Information you should know

Who is Funding the Study?
This research study is being funded by the Ovarian Cancer SPORE (Specialized Program of Research Excellence). The Ovarian SPORE (SPORE) consists of investigators and partnerships across Mayo that conducts innovative clinical trials in Ovarian Cancer. The SPORE is supported by the National Cancer Institute.

Information Regarding Conflict of Interest:

- 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 Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research, and they have determined that this Financial Conflict of 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 Conflict of 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 Conflict of 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.

4. How long will you be in this research study?

If your cancer improves or does not get worse, you will be allowed to have up to 6 cycles of study treatment. After stopping study treatment, you will be asked to keep coming to the clinic for follow up unless your cancer worsens. From that point you will be followed every 6 months for up to 5 years so that the researchers can watch your health status.

Should death occur regardless of the cause, permission for an autopsy will be requested of your family. This is important so that the researchers can further document the safety and effectiveness of this treatment. The researchers encourage you to talk to your family regarding this issue.

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

If you agree to take part in this study, you will need to have tests done to see if you can be in the study. These tests include:

- a complete physical exam during which the researchers will look at your past medical history and look at how you are doing now;
- measurement of your height and weight, blood pressure, temperature, and pulse;
- a chest x-ray to exclude the presence of tumor in your lungs;
- an echo or MUGA to assess the function of your heart

- an electrocardiogram (ECG) to look at your heart function;
- CT scans or other x-ray scans to find and measure your tumor(s);
- blood tests as part of your regular medical care;
- blood tests just for this research study.

If it is not known if you have HIV you will need to have a blood test done. If your HIV test result is positive you will need to have a second test done to make sure the results are the same. The researcher will tell you how to find medical help and counseling, as needed, and you may not be able to take part in the study. Your health insurer or you will have to pay for the cost of the repeat test, any follow-up medical care, or counseling.

- If the HIV test result is positive, it is state law that they be reported to the State Department of Health. The test results will also be put in your medical record.

Patients who are HIV positive or have other immune impairment will be ineligible for the trial. Similarly, you will not be eligible for the study if you had an increased CEA level prior to enrolling to the study or at any time in the past.

After these tests are done, the researchers will know if you are able to take part in the study. If you are able to take part, you will be scheduled to begin the study. You will need to have a catheter (like a plastic tube) placed into your abdomen in a way that will keep it secure for long-term use. This is a separate procedure and is done by a doctor. It must be done before you start the study. If it cannot be done, you will not be entered in the study. You will need to sign the consent for this specific procedure. At the same time, and through the incision created to insert the catheter, a tablespoon of fat will be removed (resected) and used to grow the stem cells that will later be injected into your abdomen. Your first study treatment will be the injection of the virus alone. If your body tolerates this well and you have no reactions or your disease does not progress or get worse at this time, then you will be able to receive the study treatment of the infected stem cells and continue on with the study.

Seven days before you actually begin the study, you will begin taking a tablet of a thyroid hormone named Cytomel® three times a day to help protect your thyroid from the effect of the radioiodine by taking this study treatment. This hormone will be given to you through the last day of the SPECT/CT scan that you will undergo.

This measles virus will be given to you in this catheter and samples of your abdominal fluid may be collected using this catheter so that you do not have to have more than one needle stick. This catheter will stay in your abdomen during the entire study. At the same time that the doctor puts this catheter in, a small piece of your tumor may be collected (this procedure is called a tumor 'biopsy'). If you happen to have abdominal fluid (ascites) this will be removed prior to administration of the virus. Samples of abdominal fluid will be examined during the study. If you do not have ascites, the researchers will do a peritoneal aspirate procedure.

For this procedure, a liter (about 4½ cups) of saline will be inserted into the catheter. Then the researchers will remove the liquid immediately afterwards using a suction. You will have this procedure done again on Days 3 and 8 of Cycle 1 and prior to each subsequent treatment.

We do not know what the highest safe dose of stem cells infected with the investigational agent MV-NIS is, so the investigators will give MV-NIS infected to three or more subjects at one dose, and evaluate the results, before increasing the cell dose given to the next group of subjects. The dose you will receive will depend upon both the number of subjects who have received this study treatment before you and the results they had. The investigator will discuss with you where your dose falls and how many subjects have been enrolled so that you may evaluate your potential risks and benefits. Since MV-NIS infected stem cells is a research drug, side effects and possible benefits at any dose are not yet known.

In this study, each 4-week period will be called a study treatment 'cycle. You will receive virus alone in the first treatment cycle, and virus infected stem cells in subsequent treatment cycles. (If virus-infected stem cells are not available, then you will receive virus alone.) You will be admitted to the Clinical Research and Trials Unit (CRTU) at Saint Mary's Hospital the evening before the first day of the study treatment and stay until the morning of Day 2 (two nights). Prior to each viral or viral/cells administration a saline lock (intravenous line) will be placed in the arm for safety purposes. A saline lock will allow us to administer medications intravenously, if necessary, while you are getting your study treatment. Subsequent study treatments will also be administered in the CRTU, with an overnight stay for Cycle 2, but no overnight stay will be required for Cycles 3-6. This overnight stay will allow investigators to collect blood, urine, throat gargle specimen(s), and tissue samples for research purposes.

Also on Day 3, 8, 15 and 23 you will need to have a urine test and throat gargle specimen(s) done in the Clinical Research and Trials Unit (CRTU).

Prior to administration of the virus on Days 3 and 8 of Cycle 1, you will have a SPECT/CT scan performed. For this scan, you will be given a small amount of radioactive iodine to drink. Two hours later, you will lie on a table while the SPECT/CT device uses x-rays and a special camera to take pictures of the radioactive iodine within your body. The SPECT/CT scan may also be repeated on Day 15 of Cycle 1 and 2. If this scan is positive, the SPECT/CT scan will be repeated again during Cycle 2.

Cycle 1 Only:	
Pre-Study	• physical exam • review of your medical history • recording of your height and weight • electrocardiogram (ECG) • MUGA/Echo • collection of blood and urine for your regular medical care • measurement of your tumor(s) by CT scan or MRI • chest x-ray • collection of urine, blood, tissue samples, and throat gargle specimen(s), for research purposes • insertion of the peritoneal catheter • peritoneal aspirate procedure • fat aspirate procedure • SPECT CT scan
7 days before starting study	• Start Cytomel
1 day before starting study	• Admit to the CRTU
Day 1	• Collection of blood samples for research purposes before and after you receive MV-NIS • You will be given the virus through the catheter in your abdomen • You will stay in the CRTU until 24 hours after the virus is given
Day 3	• Collection of blood, urine samples, and throat gargle specimen(s), for research purposes • Peritoneal Aspirate procedure • SPECT CT scan (If this scan is positive, the SPECT/CT scan will be repeated again during Cycle 2.)
Day 8	• Collection of blood for regular care • Collection of blood, urine samples, and throat gargle specimen(s), for research purposes (these will be collected in the CRTU) • Peritoneal Aspirate procedure • SPECT CT scan (If this scan is positive, the SPECT/CT scan will be repeated again during Cycle 2.)
Day 15	• Collection of blood for regular care • Collection of blood samples for research purposes • SPECT CT scan. May or may not be done based upon previous scans

Day 23	• Collection of blood, urine samples, and throat gargle specimen(s), for research purposes

If the virus is found in your urine or throat samples, then your family members may also be offered testing for immunity against the measles virus. If your family members are not immune to the measles virus, they will be offered the measles vaccine.

Cycle 2 (Day 1 of Cycle 2)

1 day before starting Cycle 2	• Admit to the CRTU
Prior to treatment in Cycle 2	• Physical exam and review of your medical history • Collection of blood and urine samples as part of your regular medical care • Collection of blood, urine samples, and throat gargle specimen(s), for research purposes (these will be collected in the CRTU) • Electrocardiogram (ECG) • Measurement of your tumor using CT scan or MRI • Peritoneal Aspirate procedure • SPECT CT scan. • Schedule is similar to the Cycle 1.You will get the measles virus infected stem cells (or measles virus alone) in the catheter in your abdomen at the CRTU and will stay in the CRTU after this administration for 24 hours.
Day 3	• Collection of blood, urine samples, and throat gargle specimen(s), for research purposes • Peritoneal Aspirate procedure • SPECT CT scan (If this scan is positive, the SPECT/CT scan will be repeated again during Cycle 3.)
Day 8	• Collection of blood for regular care • Collection of blood, urine samples, and throat gargle specimen(s), for research purposes (these will be collected in the CRTU) • Peritoneal Aspirate procedure • SPECT CT scan (If this scan is positive, the SPECT/CT scan will be repeated again during Cycle 3.)
Day 15	• Collection of blood for regular care • Collection of blood samples for research purposes • SPECT CT scan - May or may not be done based upon previous scans
Day 23	• Collection of blood, urine samples, and throat gargle specimen(s), for research purposes

All other cycles during the study:	
Prior to treatment Cycles 3-6 and at end of treatment	• Physical exam and review of your medical history • Collection of blood and urine samples as part of your regular medical care • Collection of blood, urine samples, and throat gargle specimen(s), for research purposes as an outpatient in the CRTU • Electrocardiogram (ECG) • Measurement of your tumor using CT scan or MRI • Peritoneal Aspirate procedure
Day 1	• You will get the measles virus infected stem cells or measles virus alone through the catheter in your abdomen as an outpatient at the CRTU. There is a 3 hour observation period after this infusion is done, and then you may leave the CRTU.
Cycles 3-6, Day 3 and 23	• Collection of blood, urine samples, and throat gargle specimen(s), for research purposes
One month after the 6th treatment cycle	• Examination of the abdomen by inserting a scope through a small incision in the abdominal wall. This procedure will be necessary only if your disease was not visible in the x-ray taken prior to starting your first treatment.
Every 3 months after your 6th treatment cycle	• Physical exam and review of your medical history • Collection of blood and urine samples as part of your regular medical care • Collection of blood samples for research purposes • Electrocardiogram (ECG) • Measurement of your tumor using CT scan or MRI
3 and 12 months after your disease has progressed	• Physical exam and review of your medical history • Collection of blood and urine samples as part of your regular medical care • Collection of blood samples for research purposes • Electrocardiogram (ECG) • Measurement of your tumor using CT scan or MRI

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

MV-NIS

While you are taking part in this study, you are at risk for these side effects. You should talk to your study doctor and/or your medical doctor about these side effects. The safety of administering MV-NIS is not known. The side effects discussed below are based upon the illness seen with measles infection and common reactions seen after measles vaccination.

Although the strain of the virus used in this study was derived from the vaccine lineage, it is not known if this virus is more or less attenuated than other vaccine strains. The route of administration is different and the doses of virus used in this study can be significantly higher than those given at the time of vaccination. Therefore, there may be other side effects that are not known. Other drugs may be given to lessen side effects. Many side effects go away shortly after the viral treatment is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death.

Common side effects of the virus:

- Abdominal discomfort resulting from administration of the viral solution to the peritoneal cavity.
- Fatigue

Less common side effects:

- Moderate to high fever lasting 1-2 days, starting within a day or two of the virus administration
- Low white blood cell count (the blood cells that fight infection)

Rare side effects:

- An acute allergic reaction with shortness of breath, rash, wheezing, and low blood pressure, which in rare cases can be fatal.
- Reactions at the injection site such as wheal, flare or urticaria
- Reaction or infection of the lining of the abdomen (peritoneum) after administration of the virus in the abdominal cavity (peritonitis), or spleen infection.
- A decrease in the number of platelets in the blood, resulting in the potential for increased bleeding and decreased ability for clotting.
- Diarrhea
- Auto-immune or immune-complex disease
- Infection with measles outside the abdomen
- Prolonged fever
- Joint pain
- Cough and runny nose
- Skin rash
- Decrease in delayed type-hypersensitivity skin test responses, which can increase your susceptibility to certain types of infection.

In addition, people rarely develop pneumonia or encephalitis after exposure to measles virus, although this is unlikely in subjects with measles immunity.

Should you develop a measles systemic infection, treatments of potential benefit, although not FDA approved, include immune globulin and ribavirin.

A blood drawing may cause minimal discomfort and a small risk of bleeding, bruising, or infection at the needle site.

Examination of the abdomen by inserting a scope through a small abdominal incision (one month after 6th treatment cycle): This procedure only applies to people who did not have visible disease in the x-ray taken before the study started and throughout the study. Inserting a scope through a small incision in your abdominal wall, as part of this procedure, may result in a small risk of bleeding, infection, or abdominal discomfort.

SPECT CT scan
You will be exposed to radiation during these tests. The amount of radiation you would get has a low risk of harmful effects.

Cytomel®
The risks of Cytomel® may include:

- irregular heartbeats
- sweating
- headaches
- shortness of breath
- vomiting

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

Electrocardiogram (ECG)
This test uses small sticky pads that are placed on your chest and limbs to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. Chest hair may need to be shaved prior to the placement of the sticky pads.

Echocardiogram (ECHO)
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.

Pregnancy/birth control
Pregnancy and birth control measures will not be addressed, for in order for the subject to be included in the study, they must have had a prior bi-lateral oophorectomy (removal of the ovaries). A person cannot get pregnant if this is surgery was done.

7. 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, Dr. E. Galanis 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.

8. 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?
If you have side effects from the study treatment, you need to report them to the researcher and your regular physician, and you will be treated as needed. Mayo will bill you or your insurer for these services at the usual charge. Mayo will not offer free medical care or payment for any bad side effects from taking part in this study.

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

There is no guarantee that this study will make your health better. However, the information gained in this study may help doctors provide better treatment for cancer patients in the future.

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

You do not have to be in this study to receive treatment for your condition. Other choices of treatment for your disease include other investigational treatments, radiation therapy, biotherapy, and chemotherapy. You should talk to the researcher and your regular physician about each of these choices before you decide if you will take part in this study. You also have the option of choosing no treatment.

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

You will not need to pay for any tests and procedures which are done just for this research study, nor for the investigational drug. Mayo will pay for the measles virus (MV-NIS) that you receive during this study. The tests and exams done just for the research study include the blood tests done just for research purposes, the peritoneal aspirates and tumor biopsy, the placement of the catheter in the abdomen and the surgical assessment of the effect of the treatment if necessary. This includes the Cytomel, I-123, and the SPECT/CT scans. You will not be billed for room and board or nursing charges while in the Clinical Research Unit. However, you may be billed for other expenses such as medications prescribed at the time of discharge.

You and/or your health plan will need to pay for all other tests and exams that you would normally have as part of your regular medical care. These tests and exams include standard blood tests, x-rays, and CT scans that measure your tumors. Should side effects occur, you and/or your health plan might also have to pay for other drugs or treatments which are given to help control side effects.

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

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

13. What will happen to your samples?

We would like to keep your sample for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Other 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). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my sample to be stored and used in future research of Cancer at Mayo Clinic:

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my sample to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

   ☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my sample to researchers at other institutions:

   ☐ Yes ☐ No Please initial here: _____Date: _____

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

You may request to have your sample destroyed by writing to the Principal Investigator. The address is found in the "Contact Information" section of this consent form.

Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

14. 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. Various methods are used to safeguard confidentiality. Some or all of the following may be used in this study: assigning a specific code or registration number to each participant's data and samples, research materials stored in locked areas, password protected data stored on a computer. 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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care. Researchers involved in this study at other institutions.

- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

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, 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 Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.
You can cancel your permission 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 1st Street 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.

Approval Date: **May 23, 2024**
Not to be used after: **September 14, 2024**

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 lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES

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

	/ /	: AM/PM
Printed Name	Date	Time

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.

	/ /	: AM/PM
Printed Name	Date	Time

Signature