A Study of a Novel Precision Medicine Approach For Obesity

NCT06814938

December 11, 2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **December 11, 2025**
Not to be used after: **July 29, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: **A** Novel Precision Medicine Approach For Obesity A Randomized, Multi-Center Trial

IRB: 23-006754

Principal Investigator: Andres Acosta, 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 chose not to take part.
Research Purpose	The purpose of this research is to study if the My Phenome test will predict greater weight loss response to semaglutide, a weight loss medication, in patients with obesity and a positive test result compared to patients with obesity and a negative test result. You have been asked to take part in this research because you are a healthy adult with a BMI greater than 30 interested in weight loss.
What's Involved	Study participation involves taking a weight loss medication or placebo for approximately 24 weeks. This study uses a placebo. A placebo looks exactly like the study drug, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study drug. It involves 8 visits.

	Study procedures include questionnaires, medical history and physical exam, urine pregnancy tests, blood draws, saliva samples, measuring vital signs, metabolic studies, weight loss recommendations from an obesity expert physician, an activity tracking device and downloading applications for tracking diet and exercise.
Key Information	The most notable risks in this study are those associated with taking an FDA approved weight loss medication, blood draws, answering questionnaires, and exposure to radiation. The risks associated with study participation are completely described later in this form, be sure to review them carefully. There are no costs to you for being in the study. The study may help you reach your weight loss goals. You will not be paid for your time in this study.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

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

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

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

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Andres Acosta, M.D., Ph.D. **Phone:** (507) 266-6931 **Study Team Contact:** Megan Schaefer **Phone:** (507) 266-6004 **Institution Name and Address:** Mayo Clinic 200 1st St SW Rochester MN 55905 **Principal Investigator:** Maria Daniela Hurtado Andrade, M.D., Ph.D. **Phone:** (904) 953-2381 Mayo Clinic Jacksonville 4500 San Pablo Road Jacksonville, FL 32224
▪ 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.

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

You are being asked to take part in this research study because you are a healthy adult between the ages of 18 and 65 with a BMI greater than 30 kg/m^2 and you are interested in weight loss treatment.

Why is this research study being done?

This study is being done to assess the efficacy of a saliva- based biomarker to predict response to semaglutide for the treatment of obesity.

Information you should know

Who is Funding the Study?
This study is funded by the National Institute of Health.

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.

- 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.
- One or more of the investigator has a financial interest in one of the companies sponsoring this research, providing a product for the research or whose product is the subject of this research and that Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

This study will take approximately 24 weeks to complete.

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

This study consists of 8 visits. The first visit may be in-person at Mayo Clinic or virtually. The seven additional visits are in-person at the Mayo Clinic. In some cases, the investigator may not be physically present during your visit. If this occurs, the investigator may meet with you virtually using a secure video connection (such as Zoom or Microsoft Teams). During this virtual portion of your visit, the investigator will discuss your progress, review safety information, and answer any questions you may have. The rest of your study visit (such as vital signs, labs, and any in-person assessments) will still take place at the clinic with study staff.
If you agree to be in the study, you will be asked to participate in the following:

Visit 1 (In-person or Virtual):
A virtual or in-person screening and consent visit will take place. You will be provided time to ask questions about the study. If you decide to participate in the study, you will need to sign the consent form before starting any of the study-related procedures. Visit 1 will take approximately 1-2 hours.

After the consent form is signed, you will fill out the following questionnaires to confirm your eligibility:

- Questionnaire on Eating and Weight Patterns-Revised
- Hospital Anxiety and Depression Questionnaire
- Columbia Suicide Severity Rating Scale (C-SSRS)

The study team will administer the Columbia Suicide Severity Rating Scale (C-SSRS) questionnaire to you. All other questionnaires will be sent to your email to complete and return in an electronic format.

- You will have your height, weight, waist measurement, hip measurement, pulse, and blood pressure measured.
- You will need to give a saliva sample. Your date of birth, height and weight will be provided to an outside laboratory (Phenomix) that will process your saliva sample and generate MyPhenome Test result.
- The study physician will perform a physical exam.
- Your demographics, medical history, and medications will be reviewed.
- A Garmin activity tracker will be activated to track your activity during the study.
- You will download the Garmin Connect, and Labfront, applications on your smartphone. The information required for these applications include email, password, date of birth, height, and weight You will be asked to share your Garmin app login credentials (username and password) in order for us to be able to collect data. This information will be explained to you by a member of the research team. The study team will help you set up the Garmin activity tracker and applications.
- You will download the Cronomoter diet tracking app to track calories throughout the duration of the study.
- You will be provided instructions to track your physical activity on the Garmin activity app and your food and liquid intake on Cronomoter diet app for 1 full week of your choosing before Visit 2.
- You will be asked to complete an activity tracker form in which you will provide your email and password to your Garmin Connect account.

Visit 2:
This will take approximately 2 hours to complete. You will be asked to come to the Mayo Clinic campus after fasting (nothing to eat or drink besides water) for 8 hours prior to your visit.

- You will have your height, weight, waist measurement, hip measurement and vital signs (pulse, blood pressure, respiration rate and temperature) measured.
- Your medical history and medications will be reviewed by the study team.
- The study team will assess for adverse events.
- Based on the participants' randomization, semaglutide or placebo will be assigned to participants
    - If you are eligible for the study, we will assign you by chance (like a coin toss) to the semaglutide group or the placebo group. A placebo looks exactly like the study drug, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study drug. You and the Principal Investigator can't choose your study group. You will have a 2:1 ratio of being assigned to the semaglutide group.

  - Neither you nor the Principal Investigator will know which study group you are in. However, in case of an emergency, this information will be available.
  - Your study team will provide you with instructions and teach you or your care person on how to inject the medication. If you miss your dose by more than 24 hours, please contact your study care team for instructions.
- A Dosing Diary will be given to you at each visit and returned back at each study visit with the medication.
- Dietary counselling
  - All participants will receive standard of care intensive lifestyle intervention, behavioral evaluation, and monthly follow-up from your study team. All participants will be recommended the following: 1) low-calorie diet based on their predicted by Harris Benedict resting energy expenditure minus 500 kcal per day; 2) physical activity: a goal of 10,000 steps or more per day; 3) exercise: a goal of 150 minutes or more of moderate-intensity aerobic activity (cardiovascular exercise) per week; 4) limited consumption of liquid calories (i.e. sodas, juices, alcohol, etc.).
- A member of the study team will review the information collected by the Garmin activity tracker.
- A member of the study team will review your 7-day liquid and food intake on the Cronometer diet tracker.
- Fasting clinical or research blood samples (basic metabolic panel, lipid panel, HbA1C, and hsCRP)
- A urine sample will be collected for a pregnancy test from women who can get pregnant if it was not done within 48 hours of this study day. The results of this test must be negative in order for you to continue with the rest of the study.
- Baseline body composition will be measured using a DEXA scan or a bioimpedance device (bioimpedance available only at Florida site). You will have your total body fat measured using an external machine (called DEXA) that uses a very small dose of x-rays. This involves lying (face up) on an x-ray bed for about 15 minutes. The baseline scan will be done after you enroll and within 5 days after your first-in-person visit. Both scan types are safe and non-invasive
- The study team will administer the Columbia Suicide Severity Rating Scale
- All other questionnaires will be sent to your email to complete and return in an electronic format. These questionnaires are assessing mood, physical activity levels, attitudes, body image, diet, and eating behavior These questionnaires include:
  - AUDIT-C Alcoholism Screening Test
  - Eating and Weight Patterns-Revised
  - Three Factor Eating
  - The Weight Efficacy Lifestyle (WEL)
  - Physical Activity Assessment

- Physical Activity Stages of Change
- Exercise Regulations (BREQ-3)
- Barriers to Being Active
- Hospital Anxiety and Depression
- 24-hour Diet Recall
- My Eating Behavior

Visits 3, 4, 6, and 7:
This will take approximately 1-2 hours to complete. You will be asked to come to the Mayo Clinic campus.

- You will be asked to complete a 24-hour diet recall through Cronometer diet tracker the day prior to each visit.
- You will have your height, weight, waist measurement, hip measurement and vital signs (pulse, blood pressure, respiration rate and temperature) measured.
- Your medical history and medications will be reviewed with the study team.
- A member of the study team will review the information collected by the Garmin activity tracker.
- Dietary counselling:
- All participants will receive standard of care intensive lifestyle intervention, behavioral evaluation, and monthly follow-up from your study team. All participants will be recommended the following: 1) low-calorie diet based on their predicted by Harris Benedict resting energy expenditure minus 500 kcal per day; 2) physical activity: a goal of 10,000 steps or more per day; 3) exercise: a goal of 150 minutes or more of moderate-intensity aerobic activity (cardiovascular exercise) per week; 4) limited consumption of liquid calories (i.e. sodas, juices, alcohol, etc
- You will receive the study medication or placebo.
    - You will return medication and Dosing Diary at these visits. You will receive a new Dosing Diary with additional medication.
- You will meet with a member of the study team for a brief assessment of your injection site, medications reconciliation and adverse events.
- The study team will administer the Columbia Suicide Severity Rating Scale
- Women who can get pregnant will be given a urine pregnancy test kit and instructions on how to complete the home pregnancy test at Visit 4. You will be asked to complete the pregnancy test at home and share the results of the pregnancy test with the study team at visit 5.

Visit 5:
This will take approximately 2 hours to complete. You will be asked to come to the Mayo Clinic campus after fasting (nothing to eat or drink) for 8 hours prior to your visit.

- You will be asked to complete a 24-hour diet recall through the Cronometer diet tracker the day prior to your visit
- You will have your height, weight, waist measurement, hip measurement and vital signs (pulse, blood pressure, respiration rate and temperature) measured.
- Your medical history and medications will be reviewed by the study team.
- Fasting clinical or research blood samples (basic metabolic panel, lipid panel, and HbA1C)
- A member of the study team will review the information collected by the Garmin activity tracker.
- Dietary counselling:
- All participants will receive standard of care intensive lifestyle intervention, behavioral evaluation, and monthly follow-up from your study team. All participants will be recommended the following: 1) low-calorie diet based on their predicted by Harris Benedict resting energy expenditure minus 500 kcal per day; 2) physical activity: a goal of 10,000 steps or more per day; 3) exercise: a goal of 150 minutes or more of moderate-intensity aerobic activity (cardiovascular exercise) per week; 4) limited consumption of liquid calories (i.e. sodas, juices, alcohol, etc.).
- Women who can get pregnant will share the results of the home pregnancy test they completed prior to this visit. The results of this test must be negative in order for you to continue with the rest of the study.
- You will receive the study medication or placebo.
    - You will return medication and Dosing Diary at these visits. You will receive a new Dosing Diary with additional medication.
- You will meet with a member of the study team for a brief assessment of the injection site, medications reconciliation and adverse events.
- The study team will administer the Columbia Suicide Severity Rating Scale

Visit 8 (Or End of Study or Early Termination):
This will take approximately 2 hours to complete. You will be asked to come to the Mayo Clinic campus after fasting (nothing to eat or drink) for 8 hours prior to your visit.

- You will have your height, weight, waist measurement, hip measurement and vital signs (pulse, blood pressure, respiration rate and temperature) measured.
- Your medical history and medications will be reviewed by the study team.
- The study physician will perform a physical exam.
- Body composition will be measured using a DEXA scan or a bioimpedance device (bioimpedance available only at Florida site. You will have your total body fat measured using an external machine (called DEXA) that uses a very small dose of x-rays. This involves lying (face up) on an x-ray bed for about 15 minutes. End of study body composition scan via DEXA or bioimpedance, to be performed at any point between Visit 7 and up to 5 days before Visit 8.

- Fasting clinical or research blood samples (basic metabolic panel, lipid panel, HbA1C, and hsCRP).
- A urine sample will be collected for a pregnancy test from women who can get pregnant if it was not done within 48 hours of this study day.
- You will meet with a member of the study team for a brief assessment of your injection site, medications reconciliation and adverse events.
- Return all unused medication and Dosing Diary.
- The study team will administer the Columbia Suicide Severity Rating Scale
- All other questionnaires will be sent to your email to complete and return in an electronic format. These questionnaires assess mood, physical activity levels, attitudes, body image, diet, and eating behavior . These questionnaires include:
    - AUDIT-C Alcoholism Screening Test
    - Eating and Weight Patterns-Revised
    - Three Factor Eating
    - Weight Efficacy Lifestyle (WEL)
    - Physical Activity Stages of Change
    - Exercise Regulations (BREQ-3)
    - Barriers to Being Active
    - Hospital Anxiety and Depression
    - 24-hour Diet Recall
    - My Eating Behavior
    -
- A member of the study team will review the information collected by the Garmin activity and Cronometer diet tracker.

The total amount of blood drawn for these tests during the study will be approximately 38 tablespoons.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance. There will be a few tests that will be reported to your medical record during your participation in this study. The tests are basic metabolic panel, lipid panel, and HbA1C.

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

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

Medication: SEMAGLUTIDE : The study medication is an FDA approved weight loss medication. Rare side effects include Risk of Thyroid C-Cell Tumors, Acute Pancreatitis, Acute Gallbladder Disease, Hypoglycemia, Acute Kidney Injury, Hypersensitivity, Diabetic Retinopathy Complications in Patients with Type 2 Diabetes, Severe Rash or Itching, Heart Rate Increase, Suicidal Behavior and Ideation. The most common side effects include abdominal bloating, nausea, vomiting, diarrhea, gastrointestinal malaise, constipation, fatigue, and changes in mood.

Radiation: You will be exposed to radiation during the DEXA Body Composition Scan in this research study. The amount of radiation you will receive has a low risk of harmful effects.

Bioimpedance Testing: Bioimpedance is safe for most people. It uses a very small, painless electrical signal to measure body composition. You will not feel the signal.

Potential risks or considerations include:

- **Minor skin irritation:** Very rare but may occur at electrode contact points (mostly in clinical-grade devices with sticky pads).
- **Inaccuracy with certain medical devices.** People with implanted electronic devices (like pacemakers, defibrillators, or neurotransmitters) should not undergo bioimpedance testing, as the signal could potentially interfere with the function of those devices.
- **Hydration sensitivity:** Results may vary depending on your hydration status, recent exercise, or food intake. These are not risks but may affect test accuracy.

Questionnaires: Some questions you will be asked to answer in the study questionnaires may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

Pregnancy and Birth Control:
Women of child-bearing-potential will be able to participate in this study if they have a negative pregnancy test and agree to use acceptable birth control (see below) since the risks to an unborn child are either unknown or potentially serious.

- Surgical sterilization

- Approved hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

There is not enough medical information to know what the risks might be to a breast-fed infant or to an unborn child carried by a woman who takes part in this study. Breast-feeding mothers must stop breast-feeding to take part in this study.

As part of this study pregnancy testing is required for all women who are able to become pregnant. You will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to take part in the study. A pregnancy test will be done every 3 months. If the pregnancy test becomes positive, you will not be able to continue to participate in the study.

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

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

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.

If you decide to stop participating in this study or you are stopped from taking part in the study by the principal investigator or Mayo Clinic you must return the wearable activity tracker to the study team.

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. However, the study medication may help you reach your weight loss goals.

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

You are free to choose to participate in this study. If you do not participate you can contact your primary care physicians to refer you to a weight management clinic.

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 which are done just for this research study.

These tests and procedures are:

- Questionnaires
- Physical exam
- Vital signs
- Blood tests
- Saliva tests
- Urine pregnancy tests
- Body Measurements
- DEXA-Body Composition scan
- Study medication/placebo for 24 weeks
- Activity tracker (Garmin)
- Diet and Activity Tracking Applications (Cronometer, Garmin Connect, and Labfront)

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, including co-payments and deductibles.

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; however, you will be able to keep your fitness tracker upon study completion.

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?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

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.

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. Every subject in this study will be given a unique number at entry to the study.

This number will be linked to the subject's medical record number in a password – protected computer database, and in paper form in a secure location at the Mayo Clinic. You can exercise your rights to access, correct, modify, or delete your information at any time by contacting the study staff.

This information will be stored in locked filing cabinets or in computers with security passwords.

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

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

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

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.
- 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.

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.

Approval Date: **December 11, 2025**
Not to be used after: **July 29, 2026**

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.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

MAYO CLINIC

Name and Clinic Number

Approval Date: **December 11, 2025**
Not to be used after: **July 29, 2026**

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