The Effects of Glucagon on Hepatic Metabolism

NCT05500586

2/26/2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **February 26, 2025**
Not to be used after: **February 25, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: The Effects of Glucagon on Hepatic Metabolism

IRB#: 22-000113

Principal Investigator: Dr. Adrian Vella 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 determine the action of glucagon (a hormone made by your body) on hepatic amino acid, glucose, and lipid metabolism in lean and obese subjects with and without type 2 diabetes mellitus and varying degrees of hepatic steatosis (fatty liver disease). You have been asked to take part in this research because you are healthy or have type 2 diabetes.
What's Involved	The study will take 4 weeks or more to complete and will require 2 visits. We will ask that you arrive for the outpatient screening visit after fasting for at least 8 hours. The second visit will be an overnight study visit to the Mayo Clinic Clinical Research Trials Unit at Saint Marys Campus.

	You will complete blood draws, a DEXA scan, ECG (electrocardiogram), an Oral Glucose Tolerance Test (for non-diabetic participants), questionnaires, an MRI, and infusions.
Key Information	Participating in this study involves risks associated with blood draws, placement of a urinary catheter, peripheral (hand/arm) line placement, femoral (thigh) line placement, catheter placement, deuterated (heavy) water ingestion, intravenous infusions, and exposure to radiation. If you take medication for your diabetes, you will be asked to discontinue your medication for 3 weeks prior to the overnight study visit and remain off your diabetes medication for the duration of the study. These risks 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 goal of the study is to gather information; you will not directly benefit from participation.
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:** Dr. Adrian Vella **Phone:** (507) 284-3754 **Study Team Contact:** Amy O'Byrne, RN: (507) 255-8547 Jeanette Laugen: (507) 255-8110 Amy Zipse: (507) 255-0907 **Institution Name and Address:** Mayo Clinic 200 First Street, SW Rochester, MN 55905
▪ 3Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 either healthy or have type 2 diabetes. The plan is to have about 60 people take part in this study at Mayo Clinic.

Everyone in this study will receive Somatostatin, which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study.

Why is this research study being done?

The control of blood sugar depends on the opposing actions of two hormones – insulin and glucagon. While the action of insulin on the liver is well understood, that of glucagon is not – especially after meals. The aim of this study is to better understand the effects of glucagon on the liver and how it is changed by obesity and by type 2 diabetes.

Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the 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?

It will take you 4 weeks or more to complete this research study. During this time, we will ask you to make 1 outpatient screening visit and 1 overnight study visit to the Mayo Clinic Clinical Research Trials Unit (CRTU) at Saint Marys Campus (SMC).

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

Screening Visit:

After an overnight fast of 8 hours, you will be asked to come to the Clinical Research Trials Unit (CRTU) at approximately 7:00 am. If you agree to be in the study, you will be asked to sign this consent form. The Screening Visit will take about 5 hours. During this visit, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why. At this visit we will:

- Ask you about your medical history and medications
- Give you a limited physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Test your urine for pregnancy if you are a female able to become pregnant
- Do an electrocardiogram (ECG)
- Do a Dual Energy X-ray Absorptiometry Scan (DEXA). This machine uses a small amount of radiation to determine the amount of fat and muscle in the body. During this test you will be asked to lie flat on a special table and the scanner will pass over your body. This will take less than 30 minutes.
  If you have had a DEXA scan in the last 3 months as part of the Vella Lab research studies or another Mayo research group, and your weight is stable (+) or (-) 5 pounds, you will not be re-tested, and previously obtained values will be used.
- Meet with a nutritionist for instructions on a weight-maintenance/caffeine free diet (55% carbohydrate, 30% fat, 15% protein) for at least 3 days prior to the study visit.
- Give you questionnaires to fill out about your physical activity and alcohol intake. We hope that you will answer all the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 15 minutes to complete.

- Do an MRI (Magnetic Resonance Imaging) to measure liver fat. An MRI is a non-invasive medical imaging technique used to form pictures of the organs in the body. The MRI machine looks like a long narrow tube that is open on both ends. You will lie down on a movable table that slides into the opening of the tube. A technologist monitors you from another room. You can talk with the person by microphone. The MRI machine creates a strong magnetic field around you and radio waves are directed at your body. The procedure is painless. You do not feel the magnetic field or radio waves. During the MRI the internal part of the magnet produces a thumping noise. You may be given earplugs or have music playing to help block this noise. An MRI can last from 15 to 60 minutes. You will be instructed to hold still because movement may blur the images.

Only for non-diabetic participants: An Oral Glucose Tolerance Test (OGTT) will be done to ensure you have an adequate response to a glucose challenge. This test requires you drink a liquid containing sugar and water. Blood will be drawn at baseline, 10, 20, 30, 60, 90 and 120 minutes after the drink is finished, for measurement of glucose concentrations in the blood. A plastic needle will be placed in your hand at the beginning of the study to facilitate blood draws without the need for repeated needle sticks. This line will be used to withdraw blood. If you have had an OGTT in the last 3 months as part of the Vella Lab research studies or another Mayo research group, and your weight is stable (+) or (-) 5 pounds, you will not be re-tested, and previously obtained values will be used.

After all this is completed, the plastic needle will be removed, and you will be free to go home after eating a meal.

If eligible for the study and taking medication for type 2 diabetes, we will ask you to stop taking your diabetes medication for 3 weeks prior to the overnight study visit. This “washout period” allows your regular medications to leave your body before participation in the overnight study visit. Without these medications, your diabetes may get worse. If you are taking insulin, this can be continued after instruction on dose adjustment. If you are not on insulin, a new prescription of insulin may be provided should it be required. You will be instructed to measure your glucose twice daily using your home glucose meter and contact the study team (at the number provided in this consent form) for a fasting blood glucose greater than 150 mg/dL or a post meal glucose greater than 200 mg/dL 2 hours after eating.

You will be asked to eat a weight maintenance diet (55% carbohydrate, 30% fat and 15% protein) for at least 3 days prior to the study visit.

Study Day

You will be admitted to the CRTU at SMC, around 5:00 pm the evening before the study day and stay overnight. You will eat a caffeine free, standardized evening meal and then will remain fasting except for sips of water. Women who can become pregnant will have a urine pregnancy test at this time.

Blood samples will be drawn at 10:00 pm prior to 3 doses of deuterated (heavy) water given throughout the night. Heavy water contains deuterium, which is "heavier" than hydrogen, which is present in regular water. Deuterated water looks and tastes like regular water. It is not radioactive.

At about 5:30 am, an IV line will be place in a forearm vein used to reinfuse blood drawn from the other lines that we will not need to keep. A second and third IV line will be placed in each arm and be used for infusions. A urinary catheter will be placed at this time.

Subsequently you will be transferred to the radiology suite at Saint Marys Campus, where a hepatic vein catheter (the vein that drains the liver) will be placed via the femoral vein (vein in the groin). A femoral artery catheter (the large artery in the thigh) will also be placed. This procedure will be done by a skilled, experienced interventional radiologist under x-ray guidance (fluoroscopy). The vascular access procedure involves the insertion of a flexible and sterile, thin plastic tube (catheter) into a blood vessel to provide an effective method of drawing blood during the study procedures. The radiologist will determine the most appropriate site (left/right groin). The overlying skin will be cleaned and covered with a sterile surgical drape. The radiology team will wear sterile gowns, gloves and masks during the procedure. You will be positioned on your back and the radiologist will numb the area with a local anesthetic. This may briefly burn or sting. The radiologist will make a very small incision at the site. You may feel some pressure when the catheter is placed. Your vital signs and heart rate will be monitored throughout the procedure.

You will return to the CRTU from the radiology suite, at approximately 7:00 am. The following infusions will start and continue until the end of the study (2:00 pm): A radioactive IV tracer of glucose, Leucine (an amino acid) Approximately 9:00 am Palmitate (a stable tracer) will start and run until the end of the study, at the same time we will also start Indocyanine green (a green dye that measures the blood flow across the liver and leg) , this will run intermittently until the end of the study..

At about 10:00 am, the following infusions will start and continue until the end of the study (2:00 pm): Another IV radioactive tracer of glucose. This infusion rate will be modified depending on the measured glucose concentration and adjusted to maintain blood sugar (glucose) levels of 160 mg/dL.

Additionally, at this time infusions of insulin, glucagon, somatostatin (hormones) and Clinisol 15% (an amino acid) will start. Everyone in this study will receive Somatostatin, which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study. We will draw blood samples from your IV and femoral lines, at frequent intervals. At the end of the study (2:00 pm), all infusions will be stopped, vascular catheters will be removed (by the Principal Investigator), peripheral IV's and the urinary catheter removed. To avoid bleeding or bruising at the femoral puncture site, pressure will be applied for 10 minutes over the site of the groin catheter.

You will need to lie flat and keep your leg straight during the study and for 4-6 hours following the study, to prevent complications. You will not be permitted to get out of bed or use the restroom during this period. You will be dismissed from the CRTU later that evening (approximately 6:00 to 8:00 p.m.), after you eaten a meal, voided, and a member of the study team has seen you. You will be provided with written instructions on care of your femoral puncture site and a phone # to contact the study team for any questions or concerns.

Avoid the following activities for 3 days following the study visit:

- No lifting of more than 10 pounds (gallon of milk)
- Repetitive or extremes of motion (biking, aerobics, dancing)
- Straining with activity or bowel movements
- Sexual activity
- Squatting
- Swimming
- On the day of the procedure, apply pressure over the sit when coughing or sneezing
- No tub baths
- You may remove the bandage 24 hours after your procedure
- No driving for 24 hours
- The study team will contact you 3-5 days after the study for follow up

At the completion of this visit you would have completed your participation in this study. Patients with type 2 diabetes mellitus will subsequently resume their prior glucose lowering medication.

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.

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

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

Blood Sampling: The study will require approximately 550 mL (one pint) of blood drawn over the period of study. Once enrolled in the study, you should not donate blood or participate in another research study for 12 weeks. The risks of drawing blood include light-headedness and fainting, pain, bruising, or rarely, infection at the site of the needle stick.

Radiation: You will be exposed to radiation in this research study. Radioactive IV tracers will be used in the study. Glucose tracers are used to follow a chemical process or a complex sequence of biochemical reactions. These tracers are not known to cause any clinically detectable pharmacological effects and are used to obtain information regarding glucose metabolism. A machine called a DEXA scanner will be used to measure your body fat. This machine uses a small amount of radiation to determine the amount of fat and muscle in the body. Fluoroscopy is an imaging technique that assists the radiologist in placing the vascular catheters. A continuous X-ray image is projected on a monitor. This assists the radiologist in guiding the catheter. The amount of radiation you will receive has a low risk of harmful effects.

MRI: There are no known harmful effects from exposure to magnetic fields or radio waves used in making MRI images. Hearing damage and thermal burns can be associated with MRIs; however, you are given earplugs for the noise and are asked to alert health care team if skin becomes hot.

Electrocardiogram: Small patches, called electrodes, are applied to the skin during the electrocardiogram (ECG). It may be necessary to shave some hair, so the electrodes stick to the skin. There may be some skin irritation from the electrodes.

Oral Glucose Tolerance Test (OGTT): The drinking of a sweet drink (glucose and water) has been associated with nausea and vomiting which is usually mild and resolves quickly on its own.

Vascular Catheter Placement (IV): Complications such as allergic reactions; infection, bruising, or discomfort at the site of the needle (venipuncture site); or clotting of the vein may result from this study. Clotting may cause temporary discomfort and may require medications for thinning the blood or local surgery. You will be observed closely for these complications and, if any occur, they will be promptly and appropriately treated.

Deuterated Water: Deuterated water can sometimes cause dizziness and vertigo. We give this in 3 small doses to reduce this risk. We also give this at night while laying down to further reduce associated risks.

Femoral vein, hepatic vein, and femoral artery catheter placement. Risks associated with catheter placement include bleeding, swelling, pain or discomfort at the puncture site. Other potential risks include development of a pseudo-aneurysm (collection of blood in the tissue surrounding the blood vessel), infection, or decreased sensation in the leg of the puncture site. These catheters be placed by a skilled, experienced interventional radiologist in the radiology suite. The study team is trained in the care of these catheters. Hourly assessment of extremities will be done to monitor your pedal (ankle) pulses, temperature, movement and pain. Prolonged bedrest with restricted positioning may cause back pain or aggravate existing back pain After removal of the femoral catheter, pressure on the groin access site will be maintained to prevent hematoma (bruising) or aneurysm (a bulging or weakness in the wall of the blood vessel). You will be instructed to lie flat with leg straight throughout the study and for 4-6 hours after study completion. You will be given written activity restrictions prior to discharge and a phone contact number of the study team for any questions or concerns after discharge from the CRTU. The study team will do a phone follow-up 3-5 days after the study.

Infusions: All infusions carry a risk of allergic reactions, bruising, discomfort at the site of infusion, and infection. We will be reinfusing extra blood that we do not need to keep at the time of our blood draws. This may also cause some local irritation at the site of infusion.

Hormones are produced in our body and travel through the blood stream to tissues or organs to help them do their work. Insulin can cause hypoglycemia. Glucagon and somatostatin can cause gastrointestinal distress.

Infusion of glucose into a vein may sometimes cause pain and inflammation at the site of the infusion. Glucose infusion rates will be modified depending on the measured glucose concentration and adjusted to maintain blood sugar (glucose) levels at 160 mg/dL. Your blood glucose will be monitored at regular intervals.

Indocyanine Green contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides.

Leucine and Clinisol 15%, are amino acids. Amino acids are necessary for the body to make proteins and are mostly obtained from our diet. They can also be made in a laboratory and used as medicine. Clinisol 15% is normally used in clinical practice as part of intravenous feeding in patients who cannot eat. They are not known to cause any clinically detectable pharmacological effects.

IV glucose tracers are used to "trace" the metabolism of glucose and fat. These tracers are not known to cause any clinically detectable pharmacological effects.

Your IV lines and infusion sites will be monitored frequently during the study. Application of local therapies such as a heating pad may be used to decrease discomfort.

Hot Box: Used for Oral Glucose Tolerance test only. "The hot box" may cause some mild discomfort and is intended to make blood flow through the skin and make drawing blood easier. With prolonged exposure to continuous heat, there is a potential risk of local skin irritation or minor burn, if this occurs, it will be treated appropriately. The staff in the CRTU monitor your comfort and the skin of the hand closely.

Placement of urinary catheter. Risks associated with catheter placement include discomfort and the potential for urinary tract infection. The urinary catheter will be placed by a skilled nurse or urology technician using strict aseptic technique. The study team is trained in the care of these catheters. The catheter will be in place only for the duration of the study to minimize infection risk and ensure your comfort during the study.

Diabetes Medication: Discontinuing your diabetes medication carries a risk of increased blood glucose levels (hyperglycemia). Symptoms of high blood glucose may include increased thirst, urination, and fatigue. You will be instructed to measure your glucose twice a day, using your home glucose meter. If you do not have a meter, the study team will provide reimbursement for purchase of a meter and test strips. You should contact the study team if your fasting glucose is more than 150 mg/dL or a post meal glucose greater than 200 mg/dL 2 hours after eating.
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Pregnancy: If you are female, you must have a negative pregnancy test to participate in this study unless you cannot become pregnant.

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

- 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)

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. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

You won't benefit from taking part in this research study. It is for the benefit of research.

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

This study is only being done to gather information. You may choose not to take part in this study.

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:

- Meals and tests in the CRTU
- Blood tests
- Urine pregnancy testing if applicable
- Limited physical exam
- Medications or infusions that are part of the study
- Body composition (DEXA)
- MRI
- Radiology Line placement
- Electrocardiogram (ECG)
- Nutrition visit

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?

We will pay you $50 for the screen visit and $950 for the overnight study visit. If you are able to complete the entire study, you will receive up to $1000.
The money is for the time you spend in the study. We will provide parking vouchers to pay for your parking in Mayo Clinic facilities during study visits.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address, and Social Security number to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

If you do not have a home blood glucose meter, the study team will provide reimbursement for purchase of a meter and test strips. In order to receive reimbursement, you must provide a copy of the original receipts for those expenses.

There is a 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?

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.

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Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

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

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

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

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

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of diabetes and nutrition at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

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

☐ Yes ☐ No Please initial here: _____Date: _____

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

☐ Yes ☐ No Please initial here: _____Date: _____

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

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research.

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. Screening safety labs, vital signs and medications (IV infusions), interventional radiology report and MRI report, will become part of the medical record. Study data collected (ICL results, ECG and DEXA scan) will not become part of the medical record and cannot impact the availability and nature of care or access to healthcare. All study data will be stored in a password protected database and only the PI or his designees will have access to the data. ICL lab samples collected will be de-identified.

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.
- 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
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.

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.

MAYO CLINIC

Name and Clinic Number

Approval Date: **February 26, 2025**
Not to be used after: **February 25, 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