Effect of Genetic Variation in the GLP-1 Receptor on Beta-cell Function During Fasting and Hyperglycemia in Nondiabetic Humans

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MAYO CLINIC

Name and Clinic Number

Approval Date: **May 6, 2026**
Not to be used after: **May 5, 2027**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Effect of Genetic Variation in the GLP-1 Receptor on β-cell Function during Fasting and Hyperglycemia in Nondiabetic Humans

IRB#: 20-003984

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 find out how Glucagon-Like Peptide-1 Receptor (GLP1R), alter insulin secretion, in the fasting state and when blood sugars levels are elevated. Results from this study may help us identify therapies to prevent or reverse type 2 diabetes mellitus. You have been asked to take part in this research study because you are known to have a specific genetic variation of your GLP1R (or are found to have this variation at the Prescreen visit), are healthy and do not have diabetes. The plan is to have about 40 people take part in this study at Mayo Clinic.
What's Involved	Study participation involves 2 outpatient and 3 overnight study visits to the Mayo Clinic Clinical Research Trials Unit (CRTU) at Saint Marys Campus (SMC).

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Key Information	Participating in this study involves risks associated with blood draws, infusions, use of a "Hot Box", drinking a glucose drink and exposure to radiation. Some of the infusions can cause nausea. Potential risks and discomforts are described later in this form. Be sure to review them carefully. There are no costs to you for being in this study. This study is only being done to gather information. You won't benefit from taking part in this research study. It is for the benefit of research. You may choose not to take part 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.

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:** Adrian Vella, MD **Phone:** (507) 284-3754 **Study Team Contacts:** 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
▪ 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 we have previously analyzed your genotype via the Mayo Clinic Biobank, Tapestry, or we will be analyzing your genotype as a response to advertising, and you are healthy and do not have diabetes. If you have the genotype we are studying, you will be asked to participate in the full study. The plan is to have about 40 people take part in this study at Mayo Clinic.

Why is this research study being done?

The GLP-1 receptor (GLP1R) gene is found on the beta cells of the pancreas. Its role is in the control of blood sugar level by enhancing insulin secretion from the pancreas after eating a meal. We are doing this research study to find out how genetic variations in GLP1R alter insulin secretion, in the fasting state and when blood sugars levels are elevated. Results from this study may help us identify therapies to prevent or reverse type 2 diabetes mellitus. . We will measure the response to GLP-1 using Liraglutide (also known as Victoza), a medication approved for the treatment of type 2 diabetes. The FDA has allowed the use of this drug for investigational purposes in this study. In addition, to measure the response to GLP-1 receptor blockade we are also using an investigational compound – Exendin-9,39 – that is authorized for investigational use by the FDA in this research.

Information you should know

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

How long will you be in this research study?

It will take you about 16 weeks to complete this research study. During this time, we will ask you to make 2 outpatient and 3 overnight study visits 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?

PreScreen Visit

You will be asked to come to the CRTU. If you agree to be in the study, you will be asked to sign the consent form. We would then draw a blood sample for DNA. This sample will then be analyzed for genotype to see if you are eligible to return for the screen visit. Only interested subjects previously not genotyped through Biobank will need to be prescreened.

Screening Visit:

You will be asked to come to the CRTU for a screening visit after an 8 hour fast. If you did not have a prescreen visit and agree to be in the study, you will be asked to sign the consent form. The Screening Visit will take about 4 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)
    - 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 each study visit
- Give you a questionnaire to fill out about your physical activity
    - We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaire will take about 15 minutes complete.
- Finally, a test (Oral Glucose Tolerance Test - OGTT) to ensure you have an adequate response to a glucose challenge will be performed. 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 and your hand will be placed in a "hot box." Your hand will remain in the "hot box" until the end of the study (a total of 2 hours). 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 leave the CRTU.

If you are eligible to take part in the study, you will be asked to eat a weight maintenance/caffeine free diet (55% carbohydrate, 30% fat and 15% protein) for at least 3 days prior to each study visit. Subsequently, there will be 2 study days performed 1 week apart in random order (i.e. as in the flip of a coin). With the 3rd study day being approximately 12 weeks after the finish of the 2nd study day.

Study Day 1 (Saline):

You will be admitted to the CRTU at about 5:00 pm the evening before the study day and stay overnight. You will eat 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.

At about 5:30 am the next morning, a plastic needle will be placed in one of your hands. This line will be used to withdraw blood and your hand will be placed in a "hot box." Your hand will remain in this "hot box" until the end of the study visit. The "hot box" is a large plastic box that blows warm air over your hand. The temperature will not be greater than 131 degrees F or 55 degrees C.

A second IV line will be placed in the opposite arm and be used for infusions. At about 6:00 am, you will receive a radioactive IV tracer of glucose which will continue until the end of the study (until 12:30 pm). At about 9:00 am, another IV radioactive tracer of glucose will start. This infusion rate will be modified depending on the measured glucose concentration and adjusted to maintain blood sugar (glucose) levels of 160 mg/dL. Saline will be infused from 7:00 am until 12:30 pm and an IV bolus of a hormone (glucagon) will be given at 12:00 pm. Blood samples will be drawn at various intervals throughout the study.

At approximately 12:30 pm, the study visit will end and all infusions and plastic needles will be discontinued. You will be free to go home after eating a meal.

Study Day 2 (GLP-1):

This second study visit will be identical to Study Day #1. However, in this study, instead of saline, Liraglutide – also known as Victoza (a drug used to treat type 2 diabetes) will be given subcutaneously (as an injection under your skin) at 6:00 am. This is a medication that is similar to a hormone that is normally made by the body to stimulate insulin secretion after a meal. This hormone is called Glucagon-Like Peptide-1 (GLP-1).

Study Day 3

This third study visit will be identical to Study Day #1. However, in this study, instead of saline, Exendin-9,39 will be infused from 7:00 am to 12:30 pm. Exendin-9,39 is a protein that is similar in structure to GLP-1 but interferes with the binding of GLP-1 to its receptor thereby blocking its actions. This study will be done approximately 12 weeks after the end of the 2nd study day.

At the end of the third study visit, you would have completed your participation in this study.

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?

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 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. 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. The amount of radiation you will receive has a low risk of harmful effects.

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.

Vascular Catheter Placement: 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.

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

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

All hormone infusions carry a risk of allergic reactions, bruising, infection and discomfort at the site of the infusion. You will receive an infusion Exendin-9, 39. This hormone is still experimental and not approved by the U.S. Food and Drug Administration (FDA). However the FDA has allowed the use of Exendin-9, 39 in this research study. Exendin-9, 39 blocks the actions of specific hormones called 'incretins' that are produced by the gut in health.

GLP-1 and Liraglutide (Victoza) which is based on this hormone are examples of these incretin hormones and is used to stimulate insulin secretion. It can sometimes make you feel full (as if you have eaten a large meal) or nauseous, constipation or diarrhea, and occasionally cause vomiting. It can also cause your blood sugar to go low (hypoglycemia). You could also have an allergic reaction to the medication.

This hormone approved by the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes and obesity. However, the FDA has allowed the use of Liraglutide in this research study.

Glucagon is a hormone produced by the pancreas to prevent blood glucose levels from dropping too low. Glucagon can also cause nausea and vomiting.

Hot Box: The "hot box" may cause some mild discomfort and is intended to make blood flow through the skin and make drawing of blood easier. It may cause some reddening of your skin. This will go away when your hand is taken out of the "hot box."

Pregnancy: If you are female, you must have a negative pregnancy test in order 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)

Confidentiality: 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
- Pregnancy testing if applicable
- Limited physical exam
- Medications or infusions that are part of the study
- Body composition (DEXA) in the CRTU
- 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.

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

We will pay you 25.00 for your Prescreen visit, upon completion of all of the overnight study visits we will pay you $600. If you do not finish the study, remuneration will be prorated ($200 per overnight visit). 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 in order to issue a check for your study participation. If you receive research payments totaling $2,000 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.

Will your information or samples be used for future research?

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

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

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

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

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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 use will not be retrieved.

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) will become part of the medical record. Study data collected (genotyping results, 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.

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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 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 <u>not</u> 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.

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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.

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Enrollment and Permission Signatures

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

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

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