MAYO CLINIC

Name and Clinic Number

Approval Date: **December 15, 2023**
Not to be used after: July 27, 2024

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Molecular Mechanisms of Exercise Benefits to Insulin Resistant People **(Insulin Resistant)**

IRB#: 19-006273

Principal Investigator: Dr. KS Nair 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 how resistance exercise improves insulin sensitivity and muscle protein quality through two important genes. You have been asked to take part in this research because you are between the ages of 50-75 and insulin resistant.
What's Involved	Study participation involves baseline study visits, which include blood draws, exercise testing, cognitive testing, brain scans, and muscle and fat biopsies. After being randomly assigned to either resistance exercise training or control group, you will have 3 months of the selected intervention. At the completion of the intervention period, you will repeat the testing done at the baseline visit.

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Key Information	Risks involved in being in this study are minimal. You may experience mild pain or discomfort during the biopsy procedures or IV placement. This study will provide data to the study team that will further the understanding of how exercise can benefit people who are insulin resistant and other factors of their health.
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. KS Nair **Phone:** (507) 284-6543 **Study Team Contact:** Rose McCain **Phone:** (507) 255-6770 **Institution Name and Address:** Mayo Clinic 200 First St. SW Rochester, MN 55905
▪ Rights 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 study because you are between the ages of 50-75 and insulin resistant.

Why is this research study being done?

This study is being done to determine how resistance exercise improves insulin sensitivity and muscle protein quality through two important genes.

Information you should know

Who is Funding the Study?

This study is funded by the National Institutes of Health. The funding agency will pay Mayo Clinic to cover costs related to running the study.

How long will you be in this research study?

You will be in the study for approximately 4 to 7 months.

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

Before beginning any research procedures, you will be asked to sign this informed consent form.

If you agree to be in the study, you will be asked to participate in the following:

A **Screening Visit** will take about 2 hours and will take place in the Clinical Research and Trials Unit (CRTU). During this visit, we will do some tests to see if you are eligible to take part in this research study. At this visit we will:

- Draw a blood sample
- Vital signs including blood pressure, heart rate, temperature
- Ask you for a urine sample
- Provide you with a physical activity monitor to wear on your hip for 2 weeks
- We will then ask you to perform approximately 1 hour of cognitive testing. These tests check your memory, thinking speed, and other aspects of your thinking.

The blood tests will check your hemoglobin (substance that carries oxygen and gives blood its red appearance), white blood cell count, platelet count, blood sugar, insulin, cholesterol, creatinine (shows how your kidneys are working), liver, thyroid, and blood clotting. Together these tests will tell us if there are any reasons for you not to be in the study. The Principal Investigator will review the results of these tests and procedures. If you are not eligible, you will be told why. Once it has been determined that you are eligible to participate in the study, you will be scheduled for subsequent study days.

Approximately 2 weeks following the screening visit, you will be scheduled for an **outpatient study visit 1**, which will involve:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Measure your body composition and bone density using a DEXA (dual-energy X-ray absorptiometry) scan. You will lie down on your back and have a scanner move over your body to measure how much muscle, bone and fat you have in your body. In the process it exposes you to a small amount of x-rays. The DEXA scan will be repeated after 3 months.
- Measure the strength of your leg muscles by having you kick against a machine with a stack of weights.
- You will also meet with a dietitian to discuss the types of foods that you like to eat.
- These outpatient tests will be repeated after the 3-month intervention.
- A VO2max test on a cycle ergometer to assess aerobic capacity. This test involves cycling on a stationary bicycle while you're hooked up to a breathing mask. The test aims to measure your rate of oxygen consumption while your heart rate is elevated. It will be a progressively difficult test.

Approximately 1 week following the outpatient visit 1, you will be scheduled for an **outpatient study visit 2**, which will involve:

- You will be asked to start fasting, take nothing by mouth except water after 7 pm the evening prior to the visit.
- You will then go to the MRI unit in the Charlton building for your MRI testing on the morning of your visit.
- A small blood sample will be taken.
- You will then undergo a special brain MRI that will not use contrast. We will not need to give you any medications for the MRI. The MRI testing will take approximately 1 hour.
- Lastly, you will have a PET/CT scan done on your brain. This is a combination scan which combines a PET scan and CT scan. A CT scan uses X-rays to create images of the skull and brain. A PET scan uses radioactive material to create images of the brain.
- Before beginning, we will check your blood glucose levels by doing a finger stick. The PET/CT scan is done with a small amount of a radioactive form of sugar, called 18F-fluorodeoxyglucose, or FDG. A small catheter will be placed in your arm to inject this compound. Once this is injected you will sit for 30 minutes before the pictures begin.
- You will be placed on a scanner bed for 10 minutes while the scans are completed.
- Afterwards you will be asked to drink fluids and go to the bathroom. This will take about 1 hour.

At least 1 week after the outpatient visit 1, you will be admitted to the CRTU for approximately 24 hours. Three days before this admission, all of your food will be provided by the CRTU, and you will be instructed to decrease your caffeine use. We will ask you to eat all of the food provided and nothing more. The amount of food you receive is expected to keep your weight stable. You will also need to stop taking any aspirin or ibuprofen from three days before to three days after your overnight stays. You will not be allowed to consume caffeinated beverages during the inpatient portion of the study.

On the evening of the third day of meals, you will be admitted to the Clinical Research Unit to stay overnight. The following will happen during your **inpatient study**:

- You will be given a standardized meal at 6:00 pm.
- We will be placing intravenous (IV) needles to give you amino acids. Amino acids are the building blocks of muscle. By giving you an amino acid that is just slightly different than the amino acids that you eat in your regular diet, we will be able to tell how much and how well your body is building your muscle. When the intravenous lines are started, you will also receive a small amount of IV fluid that contains sodium chloride.
- We will be placing a special kind of "backward" IV into your hand and then placing that hand into a "hot box." This special kind of IV is the easiest way for us to get samples of

blood during the study. The "hot box" is a clear plastic box that is heated with a very small motor to 55 degrees Celsius (131 degrees Fahrenheit).

- We will be taking frequent samples of blood throughout the study. The total amount of blood taken during the inpatient study is less than 1 pint (about as much as a standard blood donation).
- We will perform three muscle biopsies to obtain a small piece of your muscle from the upper part of one leg. The area of your leg will be numbed with Lidocaine that is mixed with a small amount of sodium bicarbonate. The Lidocaine can sting and the sodium bicarbonate decreases the amount of stinging. A needle will then be used to remove the muscle. We will take a small sample 2 hours and 7 hours after the IV fluid is started.
- Immediately following the first muscle biopsy, a fat sample will be taken from your abdomen. This involves cleaning the skin to remove any germs, numbing the skin by injecting local anesthesia with a thin needle, and then removing the fat sample similar to is what done with liposuction.
- After the second muscle biopsy, we will give you a standardized meal in the form of a milk shake and measure your blood sugar over the next 4 hours.
- We will ask that you do not donate blood for 12 weeks before the study starts and for 12 weeks following completion of the study.
- This inpatient study will be repeated after the 3 month intervention.

One to two days after the inpatient study day, you will return to the CRTU for an **outpatient study day**. This visit will last approximately 4 hours. The following will happen during your outpatient study:

- You will check in to the CRTU at approximately 6:30am after an overnight fast
- A baseline blood draw will be taken
- You will perform a single session of resistance exercise (weight lifting) with one leg.
- Immediately after the exercise, we will perform a muscle biopsy exactly as was done during the inpatient study day.
- You will be given a breakfast snack and discharged from the CRTU.

Following these study days, you will be put into one of two groups by chance (as in the flip of a coin). If you are put into the sedentary group, you will be asked to continue your normal lifestyle for the 3 month intervention period. If you are put into the exercise group, you will be asked to participate in a supervised resistance (weight lifting) exercise program. For this exercise program, you will be asked to come to the Mayo Clinic Dan Abraham Healthy Living Center four days a week, for approximately an hour each day for both upper and lower body exercises. This exercise training will last for 3 months.

At the end of the 3 month intervention period, you will be asked to return to the CRTU for the two outpatient visits and one inpatient visit described above.

If you are randomized into the sedentary group, you have the option after completing the post sedentary intervention visits to participate in the resistance training program. This will involve a 3 month intervention of supervised resistance exercise program followed by returning to the CRTU for the two outpatient visits and one inpatient visit described above for a third time.

After randomization we will ask you to complete a survey on gestational diabetes if applicable.

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

You will receive the following drugs during the study: Lidocaine and labeled amino acids.

Lidocaine usually causes a mild burning sensation when it is first given into the skin. This stinging is lessened by our adding some sodium bicarbonate. As with any medication, allergic reactions are a possibility.

You will also receive amino acids that have been changed very slightly so that we can tell the difference between the amino acids we give you from the amino acids you eat every day in your diet. Amino acids are the building blocks of protein.

The very slight changes in the amino acids do not affect the way they work in your body, and no side effects have been reported because of this change.

In addition to the IV fluids containing medications, you will receive fluids that contain sodium chloride (salt). This fluid helps keep the veins open if the other fluids are not running.

You will have blood tests. The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick. The “hot box” may cause some mild discomfort and some reddening of your skin. This will go away when your hand is taken out of the “hot box.”

To measure your blood pressure, a cuff will be placed around your arm and this will be pumped up and become tight. This can cause some temporary discomfort.

You will be exposed to radiation during the DEXA scans. The amount of radiation you will receive has a low risk of harmful effects.

Possible side affects you may experience from the muscle biopsy include bleeding, collection of blood under the skin, bruising or infection.

By applying proper pressure over the site, bleeding and bruising are usually avoided. Strict sterile precautions will be taken to avoid infection. Pain is unlikely since a local anesthetic is used. However, you may experience a deep pressure feeling at the site of the biopsy. You will have temporary discomfort for 2 to 7 days following the procedure at the site where the incision was made. In rare instances, some people have reported numbness around the biopsy site for up to one year or longer. You may have a scar from the incision.

The most common risks of a fat biopsy include pain, a small dent or bump and bruising at the site of the biopsy. The bruising may last one to two weeks. Less common risks of fat biopsies include bleeding, infection, a small scar, and numbness of the skin around the site of the biopsy. The chance of these risks is less than 1% (1 in 100). Care will be taken to reduce the chance of these risks.

The aerobic exercise (VO2 max) test may be uncomfortable because of the mouthpiece and nose clip. Breathing through the mouthpiece during the exercise can cause your throat to feel dry. We will be asking you to exercise as long as possible. Your heart rate and blood pressure will be monitored closely and the test can be stopped at any time. Participating in unaccustomed resistance exercise may include risk of injury. To reduce this risk, the exercise will be performed under the supervision of qualified study team member, which will also decrease the likelihood of injury.

Participating in unaccustomed resistance exercise may include risk of injury. To reduce this risk, the exercise will be performed under the supervision of qualified study team member, which will also decrease the likelihood of injury.

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family. The genetic testing will focus on genes involved in insulin sensitivity, not generic DNA testing.

There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Occasionally people with claustrophobia may feel too closed in and may not tolerate MRI scanning.

If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped. The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

There is a small amount of radiation exposure from the images used in the PET/CT scan. The amount of radiation you will receive has a low risk of harmful effects. There is also a minor risk of pain and bruising at the injection site.

Risk summary
Many side effects go away shortly after the intravenous infusions and muscle biopsies are stopped, but in some cases side effects can be serious, long lasting, or may never go away. Some side effects may not be known. Side effects may range from mild to severe. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

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

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

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

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

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form.

Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. 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:

- Blood tests
- DEXA scan
- Study meals
- Muscle biopsies
- Aerobic exercise (VO2 max) test
- Fat biopsies
- Cognitive function testing
- Brain MRIs
- Brain PET/CT Scans

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 Research Billing at the telephone number provided in the Contact Information section of this form.

If the results of tests or procedures performed for research may be useful for your health care, you may be notified. If you decide to follow up, any further medical testing will be considered part of your clinical care, and will not be paid for by the research study. Costs will be billed to you or your insurance.

If you have questions about any costs to you that may result from taking part in the research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs.

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?

If you are put into the exercise group, we will pay you $2600 if you complete the study.

If you are put into the sedentary group, we will pay you $800. This money is for the time you spend in this study. If you choose to participate in the resistance exercise after competition of the sedentary control arm, we will pay you an additional $2200 for $3000 in total. If you start the study but stop before finishing the study, you will receive part of this money.

If you do not complete the study, we will pay $300.00 for each inpatient study visit you complete and $100 for each outpatient visit 2 you complete.

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 $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.

Will your information or samples be used for future research?

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

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies.

Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

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Please read the following statements and mark your choices:

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

☐ Yes ☐ No Please initial here: _____Date: _____

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

☐ Yes ☐ No Please initial here: _____Date: _____

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

☐ Yes ☐ No Please initial here: _____Date: _____

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

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

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

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. The safeguards include coding data, removing identifiers before data analyses, storing electronic data files behind the Mayo firewall accessible only to study team members by password protection and by keeping hard copy of subject details in institutionally secure offices. If the results of the research are made public, information that identifies you will not be used.

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. This includes a Data Safety and Monitoring Board that includes members from other institutions outside of Mayo Clinic.

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, 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.

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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
201 Building 4-60
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.

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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