A Study of Adipose Tissue in Adaptive Responses to Exercise

NCT06053125

August 8, 2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 8, 2025**
Not to be used after: **August 7, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: The role of adipose tissue in adaptive responses to exercise

IRB#: 23-002049

Principal Investigator: Hawley Kunz, Ph.D and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to determine how exercise affects fat (adipose) tissue and how changes to adipose tissue that occur during and after exercise might improve health in aging and obesity. You have been asked to take part in this research because you are either between the ages of 18 and 35 years of age or between the ages of 65 and 85 years of age.
What's Involved	Study participation involves 2 study visits, which include blood draws, abdominal fat tissue biopsies, VO2max test on a cycle ergometer to assess aerobic capacity and DEXA scan to measure body composition.
Key Information	There are no costs to you for any study procedures. The study covers all costs for all study related procedures.

	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.

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 8, 2025**
Not to be used after: **August 7, 2026**

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:** Hawley Kunz, Ph.D **Phone:** (507) 255-2061 **Study Team Contact:** Rachel Passehl **Phone:** (507) 255-8112 **Institution Name and Address:** Mayo Clinic 200 1st 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

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

You are being asked to participate because you are either between the ages of 18 and 35 years of age, or between the ages of 65 and 85 years of age. The plan is to have about 20 people from both age groups participate in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to determine how exercise affects fat (adipose) tissue and how changes to adipose tissue that occur during and after exercise might improve health in aging and obesity.

Information you should know

Who is Funding the Study?

The National Institute of Diabetes and Digestive and Kidney Diseases and a Mayo Clinic Benefactor-Funded Career Development Award are funding the study. The National Institute of Diabetes and Digestive and Kidney Diseases and the Benefactor Funded Career Development Award will pay your study doctor or the institution to cover costs related to running 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?

You will be in this study approximately 60 days, depending on your availability and availability in scheduling. During this time, we will ask you to make 2 study visits to Mayo Clinic.

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

Screening Visit: Visit 1
This visit will take place at St. Marys hospital, Domitilla 5B in the Clinical Research and Trials Unit (CRTU). This visit will last approximately 3 hours.

- You will go over this form with the study team. The study team will be available to discuss any questions or concerns.
- You are to arrive fasted (nothing to eat or drink after 7 pm the evening before except water) for blood tests. Blood will be collected for complete blood count, Prothrombin time, Glucose, Thyroid stimulating hormone, Alanine aminotransferase, Aspartate aminotransferase, Lipid panel (total cholesterol, LDL, HDL, triglycerides, non-HDL), Creatinine, Insulin serum, HbA1c, and Free fatty acids. 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. The results for all of these tests will be available on your patient online portal.
- If you are female able to become pregnant, urine will be collected for a pregnancy test. We will disclose the pregnancy test results immediately after getting the results.
- During this visit a member of the study team will go over your medical history.
- We will conduct a physical exam including height, weight, pulse, and blood pressure.
- You will be told if you pass the screening criteria. If eligible, you will have the opportunity to meet with the dietary staff of the CRTU to discuss dietary preferences.
- You will have a Dual-energy X-ray absorptiometry (DEXA) scan to assess body composition.
- You will complete 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.

Outpatient Visit: Visit 2
This visit will take place at St. Marys hospital, Domitilla 5B in the Clinical Research and Trials Unit (CRTU). One day prior to this visit, all of your food will be provided by the CRTU for the whole day. 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. This visit will last from 7am to 4:00pm.

- You will arrive at the CRTU fasting for 12 hours.
- After check-in, we will collect a fasted blood sample.
- Throughout the study (which includes blood taken during this visit and the screening visit) we will take approximately 200mL of blood, less than half a standard donation of whole blood.
- 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 what is done with liposuction.
- After the first biopsy and blood draw, you will be asked to perform 30 minutes of exercise on a cycle ergometer exercise machine.
- Immediately after exercise, another biopsy will be taken from your abdomen and blood will be drawn.
- Three hours following exercise, an additional blood draw and abdomen biopsy will be performed.
- After all biopsies and blood draws, you will be provided with lunch.
- Once deemed stable by the investigative team you will be allowed to leave.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results of your screening blood work, pregnancy test (if applicable), and the results of your physical exam (height, weight, blood pressure, pulse) will be available in the patient portal. The results of the exercise tests, the DEXA scan, the blood draws during visit 2, and the adipose tissue biopsies are only important for research. Therefore, the results of tests done with your information and these 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?

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.

You will have an electrocardiogram. An electrocardiogram is a test that uses small sticky pads that are placed on your chest and limbs to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. Chest hair may need to be shaved prior to the placement of the sticky pads.

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 small amount of radiation during the DEXA scan. The amount of radiation from the DEXA scan has a low risk of harmful effects.

The cycle ergometer exercise 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 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.

You will have blood tests, body measurements, and blood pressure measurements that could uncover a condition you did not know you had. This can be stressful. We will fully explain any results that are not normal.

Side affects you may experience from the tissue 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 some sensation 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, people have reported numbness around the biopsy site for up to one year or longer. You may have a scar from the incision.

Risk summary
Most side effects go away shortly after the blood draws and tissue biopsies are stopped, but in rare cases side effects can be serious, long lasting, or may never go away. There is the potential for side effects may not be known. Side effects may range from mild to life-threatening. 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.

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?

There will be no direct benefit to you by 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. Your care at the Mayo Clinic or Olmsted Medical Center will not be jeopardized if you choose not to participate.

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

You will not need to pay for tests and procedures which are done for this research study. These tests and procedures are:

- Blood Tests
- Urine Collection
- Pregnancy Tests (If Applicable)
- DEXA
- VO_2max
- Adipose Biopsies
- Study Meals

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 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?

You will receive $200 for completing the entire study (both the Screening Visit and Visit 2). You will receive one payment at the end of the study. If you complete only the Screening Visit, you will receive $50.

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.

There is a very small chance that some commercial value may result from the use of your data. If that happens, you won't 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 blood and tissue samples for future research. You can still take part in this current study even if you don't want your samples 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. 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.

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.

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.

Privacy protections given by the Certificate of Confidentiality for this study do not apply to combined study results; however, they do apply to your individual information. (See separate section for information about the Certificate of Confidentiality.)

Please read the following statements and mark your choices:

I permit my blood and tissue samples to be stored and used in future research of diabetes mellitus at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

I permit my blood and tissue 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: _____

I permit Mayo Clinic to give my blood and tissue 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 found 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. 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.

All materials collected will be used for research purposes only and confidentiality will be assured by use of identification codes. Electronic data will be kept in a secure database, which is only accessible to the study investigators.

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.
- Other healthcare providers involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.

- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

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.

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 8, 2025**
Not to be used after: **August 7, 2026**

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 8, 2025**
Not to be used after: **August 7, 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