# AAV8-hCocH for Cocaine Use Disorder

NCT04884594

3/25/2025

MAYO CLINIC

Name and Clinic Number

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

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Intravenous administration of AAV8-human cocaine hydrolase to treat cocaine use disorder

**IRB#:** 20-012225

**Principal Investigator:** W. Michael Hooten, MD and Colleagues

## Key Study Information

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| This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered. | |
| **It's Your Choice** | This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. |
| **Research Purpose** | The purpose of this research is to determine the safety of a novel gene viral vector treatment for adults with cocaine use disorder.<br>You have been asked to take part in this research because you have a history of cocaine use and have expressed a desire to abstain from use. |
| **What's Involved** | Study participation involves being given a one-time infusion of study drug through a small tube inserted in your vein (IV). This requires a two night inpatient stay at the Clinical Research and Trials Unit (CRTU) in Saint Marys Hospital (SMH), followed by two years of follow-up which includes multiple visits with the study team, blood draws, urine testing and completion of questionnaires. |
| **Key Information** | All study subjects receive the actual study drug. There is no placebo used in this clinical trial. The in-patient stay is needed to observe for any reactions you may experience following the infusion. These could include but are not limited to chills, fever, fast heartbeat, low blood pressure and are a normal immune response. Additional reactions which |

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| | may occur if you experience a severe immune reaction may be fatigue, loss of appetite, muscle/joint pain, nausea, vomiting, diarrhea, rash, fast breathing, seizures, headache, confusion, hallucinations, tremor and loss of coordination. While in-patient you will be monitored closely for such a response. It would happen soon after receiving the infusion and medical treatment and medications would be available to reduce your symptoms. The study drug may cause your liver enzymes to rise for a short while. Blood work is done to test for this. In order to lessen the study drug's effect on your liver, you will need to take a daily oral steroid, prednisone, starting within two weeks prior to receiving the study drug until several weeks after receipt of the study drug. The exact dose and duration of prednisone will be determined by the primary investigator based on your blood test results. If unfavorable steroid effects occur, the prednisone dose will be reduced or tapered. If continued immunosuppression is needed you will need to take oral azathioprine daily.<br><br>Additional outcomes of the study drug could be that the treatment makes cocaine use less rewarding and you may feel less of a 'high'. There is a possibility you may have increased craving and may want to increase your cocaine use. This may be harmful to you and could lead to overdose.<br><br>You will not be asked to pay for any costs directly related to this research. |
| **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 … |
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| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator:**<br>W. Michael Hooten, MD<br>**Phone:** (507) 776-9672<br><br>**Study Team Contact:** Brenda Anderson, RN<br>**Phone:** (507) 255-7157<br><br>**Institution Name and Address:**<br>Mayo Clinic<br>200 First Street SW<br>Rochester, MN 55905 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** (507) 266-4000<br>**Toll-Free:** (866) 273-4681 |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Participant Advocate (RPA)**<br>**(The RPA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br><br>**E-mail:** researchparticipantadvocate@mayo.edu |
| ▪ Billing or insurance related to this research study | **Patient Account Services**<br>**Toll-Free:** (844) 217-9591 |

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

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

You are being asked to take part in this research study because you have been identified as having cocaine use disorder.

## Why is this research study being done?

The purpose of this study is to test the safety of a novel gene viral vector treatment for adults with cocaine use disorder. This gene regulates an enzyme (cocaine hydrolase) that breaks down cocaine into inactive substances, thereby decreasing the pleasurable feeling this drug usually provides.

For transferring the gene, a virus (adenovirus) will be used that carries the human cocaine hydrolase enzyme. Adenoviruses are common viruses that we are constantly exposed to in daily life and can cause cold-like symptoms that are mild. The gene transfer has been studied and shown to work safely in animals. This study is the first step at testing this potential therapy in people.

In this study we want to find out more about the side effects of this adenovirus (AAV8-hCocH) and what doses of are safe for people. Everyone in this study will receive AAV8-hCocH, which is experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study. We don't know all the ways that this drug may affect people. We hope the information we learn from this study will help us develop a better treatment for cocaine use disorder in the future.

## Information you should know

**Who is Funding the Study?**
The National Institute on Drug Abuse (NIDA) is funding the study. NIDA will pay the institution to cover costs related to running the study.

## How long will you be in this research study?

It will take 60 months for you to complete this research study. During this time there are about 16 study visits; one of these visits requires a 2-night stay in the CRTU at SMH. The study visits are all done at the Mayo Clinic.

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

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

Screening visit: This will occur any time from 2 weeks to 2 days prior to the in-patient visit and will take about 2-3 hours. You will meet the research team who will explain the study and review inclusion and exclusion criteria to assure you are eligible to participate. If you are willing to participate, you will sign this informed consent form. After consent Dr. Hooten will take a medical and psychiatric history with suicidality screening and conduct a physical exam with vital signs. Other testing includes your self-report of cocaine use and cocaine craving questions, a blood draw for baseline lab testing, an electrocardiogram (ECG), urine toxicology, and urine pregnancy test (if needed).

The blood draw that you have at this visit will test for HIV and hepatitis. If your HIV or hepatitis test result is positive, you will need to have a second test done to make sure the results are the same. The research team will tell you how to find medical help and counseling as needed, and you may not be able to take part in the study. Your health insurer or you will have to pay for the cost of the repeat test, any follow-up medical care, or counseling. Also, if your test result is positive, it is the state law that they be reported to the State Department of Health. The test results will also be put in your medical record.

Once the study team has received all screening lab results and determined you meet eligibility to receive the study drug, you will be given a prescription for the oral steroid, prednisone. You will take this oral medication daily with the dose gradually tapered until instructed to stop. The length of time you need to be on prednisone will be determined by the results of your lab tests in the weeks following receipt of the study drug. If unfavorable steroid effects occur, the prednisone dose will be reduced or tapered. If continued immunosuppression is needed you will need to take oral azathioprine daily.

CRTU Admission: This in-patient visit occurs over three days Study Day -1, Day 0 and Day 1.

Day -1: You will be admitted to the CRTU as an in-patient research participant. In addition to the CRTU staff monitoring, Dr. Hooten will conduct a physical exam with vital signs to assure you are still eligible to participate in the trial. You will have a urine toxicology test and be asked to self-report any cocaine use as well as complete the cocaine craving questionnaire.

Day 0: In addition to the CRTU staff monitoring, Dr. Hooten will conduct a physical exam with vital signs to assure you are still eligible to participate in the trial. You will complete questionnaires for self-report of cocaine use and cocaine craving. Blood testing will be done several times, both prior to and after receiving AAV8-hCocH infusion through an IV (a small tube inserted in a vein in your arm). The infusion takes place over 30 minutes. If possible, blood draws will be obtained from the IV; however, this may require some blood draw sticks.

Day 1: You will be monitored for 24 hours after the study drug infusion ends. In addition to the CRTU staff monitoring, Dr. Hooten will conduct a physical exam with vital signs and observe you for any adverse events. There will be blood testing and you will complete questionnaires for self-report of cocaine use and cocaine craving.

Follow-Up Visits: These visits will occur at 14 different time-points, however if Dr. Hooten identifies anything requiring closer monitoring, additional visits may be needed to assure your safety. The follow up visits vary between 15 minutes to about 1 hour each and are set to occur 7 days after receiving the study infusion, weeks 2, 3, 4, 5, 6, 7 and 9 after the infusion, and months 3, 6, 9, 12, 18 and 24 after the infusion. Study procedures occurring during follow-up visits vary according to the visit and include the following: Close observation for any adverse events, physical exam with vital signs, self-report of cocaine use and cocaine craving questionnaire, urine toxicology, urine drug assay (while on prednisone only) and urine pregnancy testing (if needed) and blood testing. Long-term telephone follow-up will take about 10-15 minutes and will occur at months 36, 48 and 60 and additional lab draw if needed for cocaine hydrolase. You will be asked if you have experienced any adverse events, self-report of cocaine use and to complete the cocaine craving questionnaire.

During this study, you will be asked questions about your emotional health and mood. Dr. Hooten will be completing the Columbia-Suicide Severity Rating Scale (C-SSRS) as part of his overall health assessment of you. The C-SSRS contains questions about suicide and this information will be assessed at the screening visit only. The reason for this is that we want to assure your emotional health is good prior to beginning the study. Cocaine use and craving is a way we can tell your response to the AAV8-hCocH infusion. At each study visit you will be asked about your cocaine use and amount of cocaine craving you experience. Completing both the cocaine use and cocaine craving assessments will only take approximately 1 minute and you can skip questions that you choose not to answer.

During this study, we will test your urine for certain drugs, like cocaine. If the urine testing done prior to receiving the AAV8-hCocH infusion shows you have taken cocaine, you can't be in this study. The results of the urine drug test won't become part of your medical record. These test results will, however, remain part of your study record.

We will test your urine for the presence of prednisone only during the time you are taking that drug. The results of that test will be part of your medical record.

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?

We don't know all the ways that AAV8-hCocH may affect people however possible reactions include:

Immune response: As a normal immune response, your body may react to the virus particles and attack them. This could show up as chills, fever part of, rapid heartbeat, and low blood pressure. Severe immune reactions may result in fatigue, loss of appetite, muscle and joint pain, nausea, vomiting, diarrhea, rashes, fast breathing, seizures, headache, confusion, hallucinations, tremor, and loss of coordination. You will be monitored for safety reasons and in case of such a response treatment and medications would be available to reduce your symptoms.

Liver function: The study treatment may cause short term elevation of your liver enzymes. Your blood will be monitored, and you will be treated with prednisone or azathioprime to lessen the effect on your liver.

Prednisone risks: Common side effects may include sleep disruption, alteration in mood, increased irritability and activity level, increased appetite and weight gain.

Azathioprine risks: Common side effects may include infection, nausea, vomiting, megaloblastic anemia (lack of vitamin B12 or folate, which results in red blood cells that don't develop normally) and leukopenia (low white blood cells).

Increased drug use: If the study treatment makes cocaine use less rewarding, you may feel less of a 'high'. There is the possibility you may experience increased craving and may want to increase your cocaine use. This may be harmful to you and could lead to overdose. Call 911 or arrange for immediate medical attention if you believe you may have overdosed.

For your safety, it is important that all substances use including cocaine and other substances be fully disclosed to your medical providers.

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

ECG: This test 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.

Many side effects go away shortly after the AAV8-hCocH is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death. Some 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.

Pregnancy: The effect of AAV8-hCocH on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant. Females capable of becoming pregnant must use birth control and refrain from getting pregnant throughout the entire 5-year study period. Urine pregnancy testing will occur at set study visits during the first 2 years following the infusion of study drug. During the long-term follow up phone calls in years 3-5, we will ask if pregnancy has occurred.

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)

If you are a sexually active male, and able to father a child, you must agree to use one of the birth control methods listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)

Male study participants must use birth control for one year following the infusion of study drug.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk, including obtaining a Certificate of Confidentiality as noted later in this consent form.

## 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 research-related injuries will be billed in the ordinary manner to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

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

This study may not make your health better. However, if the enzyme that breaks down cocaine reaches a high enough level in your body, you may notice a drop in the 'reward value' of cocaine. Animal studies show that this can stop all cocaine-seeking behavior. We do not expect the same effect in human users at the low doses used in this study; however, some may benefit by reducing their cocaine use.

## 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. At this time, there are no approved drugs for the treatment of cocaine abuse. There are various behavioral treatment programs available, including cognitive behavioral therapy, counseling, residential programs, and twelve step programs.

## 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:

- All blood tests performed at study visits: hematology, biochemistry, initial hepatitis and HIV panels, anti-AAV8 antibody, anti-hCocH antibody, hCocH, PKPD analysis, ELISpot testing and cytokine level
- All urine tests performed at study visits: urine toxicology, drug assay for prednisone, urine pregnancy test
- Electrocardiogram (ECG)
- Physical exams
- In-patient stay in the CRTU
- Study drug (AAV8-hCocH) and administration of study drug
- Prednisone or Azathioprine drug prescription

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

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

You will receive payments for each study visit you complete. Study visit payments are broken down by the type of visit.

- Screening Visit (approximately 2-3 hours) $175
- CRTU Admission Visit (3 days/2 nights) $600
- Follow-up Visit (weeks 2, 4 and 6 only; year 3, 4 and 5 if lab draw needed)
  - Labs only (approximately 15 minutes) $50 (after each visit)
- All other Follow-up Visits
  - Exam, questions, labs (approximately 1 hour) $100 (after each follow-up visit)

If you are able to complete the entire study and all visits, you will receive a total of $2,025 ($2,175 if you have to come in for blood draws at the Year 3, 4, and 5 visits).

You will receive visit remuneration by Greenphire ClinCard for each study visit you complete. In order to provide this compensation, the study team may need your Social Security number.

You will be paid using the Greenphire ClinCard, a pre-paid debit card that functions like a bank debit card. The study team will load your study payments on the Greenphire ClinCard once you complete a study visit. For Mayo Clinic employees, research payments are included in your paycheck.

If a physical ClinCard cash card must be mailed to you, it will be mailed with no funds to reduce the risk of someone intercepting and using the funds. To have the funds added to the card, you will need to call a member of the study team at a number they will provide. You will be asked to verify:

a. Last 4 digits of the card's token number (on the outside of the envelope)
b. Participant first and last name
c. Participant address
d. Participant date of birth

To get paid with the ClinCard, Greenphire will need to process certain personal information about you. Your name, address, and date of birth will be given to Greenphire ClinCard. This information will be collected from you by the study staff and given to Greenphire. If you choose to not provide the required information to Greenphire, the study team can have a check issued to you through the mail.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). You will be required to provide your Social Security number to receive any individual research payment of $300 or more, or if you receive research payments totaling $600 or more in a calendar year. Accounts Payable at Mayo Clinic will be given your name, address, date of birth, and Social Security number in order to issue payment 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?

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

## 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. Research data will be entered in and maintained using a secure database that is a web-based application, HIPAA-compliant and secure.

Data are housed behind the Mayo Clinic firewall and password-protected user access is restricted to study staff. Data security and confidentiality will be assured by using coded subject IDs with the locked master-file linking these IDs to the subject name and identifiers held by Dr. Hooten and his staff.

We have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.
The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

**The research team may share your information with:**

- DHHS, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;

- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

### Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

### Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

### How your information may be shared with others:

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

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

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

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

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

## Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.
You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
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 until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

MAYO CLINIC

Name and Clinic Number

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

## Enrollment and Permission Signatures

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

| | / / | : AM/PM |
|---|---|---|
| Printed Name | Date | Time |

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.

| | / / | : AM/PM |
|---|---|---|
| Printed Name | Date | Time |

Signature