Novel Tinnitus Implant System for the Treatment of Chronic Severe Tinnitus: An Early Feasibility Study

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April 21, 2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 21, 2023**
Not to be used after: **March 21, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Novel Tinnitus Implant System for the Treatment of Chronic Severe Tinnitus: An Early Feasibility Study

IRB#: 18-007120

Principal Investigator: Dr. Matthew L. Carlson 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 learn more about a new device called the Tinnitus Implant System, which is based off of a cochlear implant and is designed to reduce the perception of tinnitus. This study will look at how safe and effective this new device is. The FDA has approved this new device to be made and tested in research studies. You have been asked to take part in this research because you reported that you have had long-standing severe tinnitus, have tried other methods to reduce your tinnitus and they have not worked well for you, and you took part in a prior study at Mayo Clinic, IRB #17-004832 "Cochlear Promontory Stimulation for Treatment of Tinnitus: Towards Developing an Implantable Device", referred to as the Promontory Stimulation study throughout the rest of this form.

What's Involved	Study participation involves at least 22 visits over one year. The screening and enrollment visits will take about 8 hours total for a short ENT exam, questionnaires, a hearing test, a dizziness exam, and a preoperative evaluation. A second step in the screening process involves a promontory stimulation test of up to 3 sessions (if necessary). If you still qualify for the study after the screening visits, you will then undergo a 2 to3-hour operation for implantation of the device. Post-operative follow-up visits include some or all of the following at each visit: questionnaires, a brief ENT exam, asking you about any side effects or health problems since your last visit, a hearing test, a dizziness test, device activation, and/or device programming. You will be able to keep using the device after your one year of study participation, or you may decide to have the device surgically removed. If you decide to keep the device, you or your insurance will be responsible for occasional device programming if required after your study participation is over.
Key Information	The potential risks associated with study participation include temporary or permanent hearing loss (rare), impaired taste (uncommon), long-term discomfort at the surgical site (uncommon), infection at the surgical site (rare), permanent dizziness (rare), temporary or permanent facial nerve paralysis (rare), or device failure (rare). Risks that are estimated to occur in less than 20% of cases are labeled "uncommon," and risks that are estimated to occur in less than 5% of cases are labeled "rare." You will make at least 22 visits to Mayo Clinic for study-related visits over the course of your one year of participation. The study pays for the device, audiometric testing and device programming during your year of participation. However, you will pay for any occasional programming updates, if needed, after your study participation has ended. There are no FDA-approved pharmacological or medical treatments for tinnitus. Currently, the mainstream treatments for tinnitus include masking with a noise machine, cognitive behavioral therapy and sound therapy.

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:** Matthew L. Carlson, M.D. **Phone:** (507) 284-8532 **Study Team Contact:** Nicole M. Tombers, RN **Phone:** (507) 293-2445 **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 ▪ Privacy concerns related to data collected in the European Economic Area. ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** ResearchParticipantAdvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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

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

You are being asked to take part in this research study because you have had severe tinnitus for at least six months, and it has not responded to conventional management. You have also completed the study #17-004832 "Cochlear Promontory Stimulation for Treatment of Tinnitus: Towards Developing an Implantable Device."

We plan to have approximately 12 people participate in this phase of the study at the Mayo Clinic.

Why is this research study being done?

The purpose of this research is to gather information on the safety and effectiveness of a novel device called the Tinnitus Implant System. Currently there are no FDA approved medications, surgeries or therapies for treatment of tinnitus. Because tinnitus is a common condition that is disabling for many people, we hope to develop a solution to reduce or eliminate this symptom.

Information you should know

Who is Funding the Study?
A grant from the Department of Defense is funding this study and the grant provides payment to Mayo Clinic to cover the cost of running the study. A cochlear implant company, Cochlear Limited, is providing the device for this study. Cochlear Limited is a major manufacturer of cochlear implants in the United States and internationally.

How long will you be in this research study?

It will take you about one year to complete this research study. During this time, we will ask you to make at least 22 study visits to 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 after signing this consent form:

The **Screening and Enrollment** visit will take approximately 8 hours in total over a one-week period. During these visits, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you are not eligible, the Principal Investigator will tell you why. At these visits we will:

- Ask you about your medical history
- Give you a brief physical exam, including looking at how your face moves (your facial nerve function) and looking in your ears with a microscope
- Give you some questionnaires to fill out about your quality of life related to tinnitus, pain, mental health, and emotional health. We hope that you will answer all of the questions, but you can skip any questions that you do not want to answer. If you have participated in #17-004832, the Promontory Stimulation study within the last year, you do not have to repeat these questionnaires for this study's screening.
- Give you a hearing test that includes testing of tinnitus frequency and loudness, as well as ABR and OAEs. ABR (auditory brainstem response) and OAEs (otoacoustic emissions) are tests that evaluate the entire hearing system—the inner ear, the brain pathways for hearing, and the hair cells If you have participated in #17-004832, the Promontory Stimulation study within the last year, you do not have to repeat the ABR and OAE for this study's screening.
- Give you a dizziness survey and a dizziness test called video head impulse testing. If you have participated in #17-004832, the Promontory Stimulation study within the last year, you do not have to repeat this survey and test for this study's screening.
- Undergo a screening promontory stimulation test, very similar to the stimulation in #17-004832, the Promontory Stimulation study. This will be up to 3 sessions of in-office promontory stimulation to make sure you still receive clinically significant benefit like you showed in the previous study. You will also fill out 3 surveys at 9 time points before, during, and after this stimulation. If you have participated in #17-004832, the Promontory Stimulation study within the last year, you do not have to repeat this test for this study's screening.
- You will undergo a preoperative exam that is standard for patients who are scheduled for surgery; this will include a pregnancy test if you are a woman of child-bearing potential
- You will sign a standard surgical consent form prior to the surgery

Pregnant women will not be allowed to enroll in this study. Please tell the study doctor if you are pregnant or think you might be pregnant.

The **Week 2** visit will include surgical implantation of the device. The surgery typically requires 2 to 3 hours to complete; however, you should anticipate spending most of the day at the Mayo Clinic. At this visit you will check in for surgery, have surgery to implant the study device (Tinnitus Implant System), and then be observed in the recovery area for a short time before going home. This is normally an outpatient procedure.

The **Week 3** visit will take approximately 3 hours. At this visit we will:

- Give you a brief physical exam, including looking at how your face moves (your facial nerve function), looking in your ears with a microscope, and looking at your incision site.
- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness, plus ABR and OAEs if testing has shown any change in your hearing
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, and pain

The **Week 5** visit will take approximately 30 minutes. This visit is only by telephone; you do not need to come to the clinic. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Have you complete some surveys to answer questions about tinnitus, dizziness, depression, and pain

The **Week 7** visit will take approximately 4 hours. At this visit we will:

- Give you a brief physical exam, including looking at how your face moves (your facial nerve function), looking in your ears with a microscope, and looking at your incision site.
- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness, plus ABR and OAEs if testing has shown any change in your hearing
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, and pain
- You will have video head impulse testing done

The **Week 9** visit will take about 30 minutes. This visit is only by telephone; you do not need to come to the clinic. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Have you complete some surveys to answer questions about tinnitus, dizziness, depression, and pain

The **Week 10** visit is a 2-day visit and will take approximately 8 hours the first day and 4 hours the second day. At these visits we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness, plus ABR and OAEs if testing has shown any change in your hearing (first day only)
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- You will have video head impulse testing done (first day only)
- Activate the tinnitus implant and begin treatment
- An audiologist will turn on your device and program the device to the level of stimulation that is comfortable and most effective

The **Week 11** visit will take approximately 4 hours. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness, plus ABR and OAEs if testing has shown any change in your hearing
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- An audiologist will program your device

The **Week 12** visit will take approximately 4 hours. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- An audiologist will program your device

The **Week 13** visit will take approximately 4 hours. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness, plus ABR and OAEs if testing has shown any change in your hearing
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- An audiologist will program your device

The **Week 14** visit will take approximately 4 hours. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness

- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- An audiologist will program your device

The remaining visits take place between **Week 15 and Week 52** and they will each take approximately 4 to 5 hours. You will continue to come to the clinic weekly for device programming until the audiologist determines that your programming has been optimized (when your device is at the best setting for you). How many visits this takes can be different for each person. We don't anticipate that any participants will continue to need weekly programming after about week 25. After your programming has been optimized, your visits will change to once monthly. At these weekly and then monthly visits, we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- You will have video head impulse testing done once every 3 months
- An audiologist will program your device as needed

If, during the course of the study, you experience a significant reduction in tinnitus suppression from the device, you may undergo up to three more sessions of promontory stimulation to see if you still receive benefit from stimulation from an electrode placed through your eardrum onto your cochlea (the stimulation procedures you underwent during the Promontory Stimulation study IRB 17-004832). If the Principal Investigator, sponsor, and other study staff decide that there is an issue with the Tinnitus Device, you may choose to undergo a revision surgery to either adjust the electrodes or have a replacement device implanted.

The **Final** follow up visit will be at about 52 weeks, or one year, after you started the study. At this visit we will:

- Ask you about side effects or health problems since your last visit
- Give you a hearing test that includes testing of tinnitus frequency and loudness
- Give you some questionnaires to fill out about tinnitus, dizziness, depression, auditory perception, and pain
- An audiologist will program your device as needed

You will be allowed to keep using the device after your study participation is over. You may need to come in to see an audiologist for updated programming once in a while, perhaps every 6 months to 2 years depending upon your individual need. If you choose to not keep your device, you may have your device surgically removed, at the expense of the study. This is typically an

outpatient procedure that takes about 2 to 3 hours. However, you should anticipate a full day visit when including check in time, surgery and recovery time.

Clinically relevant research results will be entered into the electronic medical record and will be accessible through the patient online portal.

The Principal Investigator may want to video record informal conversations with you during your time on the study, so that you can describe your experience being in the study after the device is implanted.
The video sessions would not be more frequent than once a month, and each session would not be longer than 1 hour. The videos may be used for internal review by the study team, the sponsor Cochlear Limited, and/or for scientific professional presentations.

Please read the following statement and mark your choice:

I permit video recordings of interviews with the Principal Investigator to be made and used for research purposes:

☐ Yes ☐ No Please initial here: _____Date: _____

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

The possible risks or discomforts from being in this research study are almost the same as for patients having cochlear implant surgery, because the study device is implanted in a relatively similar location and manner.

The surgeon performing your procedure is an experienced cochlear implant surgeon who has performed several hundred cochlear implant surgeries. These risks are outlined below.

Many of these risks are very rare but must still be reviewed with you. The risks that are estimated to occur in less than 20% of cases are labeled “uncommon,” and the risks that are estimated to occur in less than 5% of cases are labeled “rare.”

- Uncomfortable sounds during stimulation
- Temporary or permanent numbness around the incision or coil site
- Ear drum perforation (uncommon)
- Temporary or permanent impaired sense of taste (uncommon)
- Excessive scar formation (uncommon)

- Swelling around the incision or coil site (uncommon)
- Permanent loss of all residual hearing (rare)
- Permanent dizziness (rare)
- Permanent worsening of tinnitus (rare)
- Infection (rare)
- Temporary or permanent pain in the region of the surgical site (rare)
- Headache (rare)
- Movement of the internal device (rare)
- Stimulation of the facial nerve (rare)
- Temporary or permanent facial nerve paralysis (rare)
- Device failure or decrease in device performance (rare)
- Cerebrospinal fluid leak (rare)
- Meningitis (rare)

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

Many side effects go away shortly after the device is turned off, but in some cases side effects can be serious, long lasting, or may never go away. Serious complications related to general anesthesia are exceptionally rare and include heart attack, stroke or 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. There may be other risks of Tinnitus Implant System that are currently unknown.

Are there reasons you might leave this research study early?

You may choose to leave the study at any time. One example of why you might consider withdrawing from the study would be if you experienced significant side-effects while using the device that the study team could not address. If you withdraw because you experienced an adverse event related to the study, you will be monitored by the study team until the event resolves or no further care is necessary.

If you decide to withdraw from the study before surgery (device implantation), then no study follow-up is required. If you decide to withdraw after device implantation, completion of the initial postoperative monitoring cycle (weeks 3, 5, 7 & 9) will be recommended to ensure appropriate recovery. If you decide to withdraw after the postoperative monitoring cycle is

complete, then no additional follow-up is required provided you did not have any adverse events identified during the course of the initial postoperative monitoring cycle. Even if you do not wish to proceed with device use, completing the questionnaires and tests can still provide us with important and useful information.

You may continue to complete these after withdrawing from treatment if you desire. Data that was collected during your study participation may still be used by the study team, even if you withdraw from the study.

If you wish to have your device explanted following study withdrawal or study completion, you may do so and all costs directly related to explanation will be covered by the study budget if the request is made within 2 years of study withdrawal or study completion.

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.

For medically or surgically related complications, or issues pertaining to device programming, you will be seen in the Department of Otolaryngology. You can call the Mayo operator at (507) 255-5123 and ask for the ENT on call physician. The nature of the side effect will determine the location and frequency of follow up visits.

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. 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?

The primary goal of this study is to develop an implant that is capable of reducing or eliminating your symptoms of tinnitus. Currently there is no cure for tinnitus and there are no FDA approved

treatments available. You were identified for this study because you have severe tinnitus that impacts your daily life and you have not found other effective methods to treat your condition.

A potential direct benefit of participation in this study is that you will receive a treatment that may reduce or eliminate your symptom of tinnitus. A secondary benefit is that you will be a part of an important research project that has the potential to help a large number of future patients.

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

You do not have to be in this study to receive treatment for your condition. Your other choices may include:

- Education and counseling
- Hearing aid use
- Sound therapy
- Cognitive behavioral therapy
- Medical therapy such as antidepressants, anticonvulsants, anxiolytics, or intratympanic medications
- Dietary supplements
- Acupuncture
- Transcranial magnetic stimulation

Currently the Tinnitus Implant System is not available outside the research study. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

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 that are done just for this research study. These tests and procedures are:

- Study surveys
- Hearing tests, including otoacoustic emissions, auditory brainstem response, and tinnitus matching

- Promontory stimulation (if necessary)
- Brief physical exams done for the study
- Preoperative evaluation
- Device implant surgery, including general anesthesia
- The Tinnitus Implant System
- Device programming during your time in the study
- Device stimulation visits
- Video head impulse testing
- Device removal surgery if you decide during or at the end of the study to have the device removed, including anesthesia

You and/or your insurance will need to pay for all other tests and procedures needed for your clinical care. You and/or your insurance may also have to pay for other drugs or treatment given to control side effects. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. Some insurers will not pay for these costs. You will have to pay for any costs not covered by your insurance.

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?

Payment will accrue as the study progresses and is not contingent upon study completion. Quarterly (every three months) payments will be made to you over the course of the 12-month study. Upon completion of the study, you will receive a cumulative payment of $600 USD. If you withdraw from the study before completion, you will receive a prorated payment.

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?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

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. Data collected for this study on paper will be kept in a secure office area. Data collected electronically will be kept on Mayo's secure password-protected network as well as in Medidata RAVE, a password-protected database that complies with HIPAA regulations. Data that is shared with Cochlear Limited, the company providing the study device, will be coded and de-identified before being shared.

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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.
- Cochlear Limited
- The Department of Defense, as part of its human subjects protection oversight activities

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this 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
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 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.

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Name and Clinic Number

Approval Date: **April 21, 2023**
Not to be used after: **March 21, 2024**

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