MC230713 / 23-005512

Neuro-Oncology Anywhere: Deploying Mayo Clinic's Remote Cognitive Assessment Battery and Wearable Device Monitoring Platform While Assessing the Impact of Metformin on Cognition and Quality of Life in Patients with History of Cranial Radiation

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC230713 Neuro-Oncology Anywhere: Deploying Mayo Clinic's remote cognitive assessment battery and wearable device monitoring platform while assessing the impact of metformin on cognition and quality of life in patients with history of cranial radiation

IRB#: 23-005512

Principal Investigator: Ugur T. Sener, M.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 gather information on the feasibility of completing serial remote cognitive, activity/sleep, and self-report assessments in patients who have previously received cranial radiation. You have been asked to take part in this research because you have previously had radiation to your head.

What's Involved	Study participation involves about the same amount of time as regular care for your disease. If you choose to take part in this study, you will have visits either virtually or at the clinic once every 3 months for up to 1 year. These visits may be combined with your regular clinic visits if you prefer. You will be given a wearable device (also known as a "smartwatch") to monitor your health data. We will collect the data from your smartwatch regularly. You will get to keep this smartwatch when the study is over. You will need to complete questionnaires on a smartphone, tablet, or computer. Half the patients in this study will also be asked to take metformin. Metformin is a pill you take by mouth with water twice a day.
Key Information	The main risks from this study are due to the metformin, which may include diarrhea, nausea, vomiting, and passing gas (flatulence). The risks associated with study participation are completely described later in this form. Be sure to review them carefully. There are no additional costs to you for taking part in this study. The costs are described later in this consent form. Be sure to review them carefully. This study is research and not guaranteed to improve your health.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Ugur Sener **Phone:** (507)284-2511 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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

There will also be a description of this research study available on http://www.clinicaltrials.mayo.edu. This website will not include information that can identify you. You can search this website at any time.

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

You are being asked to take part in this study because you are having radiation to your head or had radiation to your head in the past.

About 100 people will take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this study is to find out if patient care can be done remotely for patients having cranial radiation or who have previously had cranial radiation. We want to know if collecting data such as sleep and activity using a smartwatch, and collecting testing results on a tablet or smartphone is safe and accurate.

In addition, we will compare study outcomes between patients who get metformin and those who do not.

Information you should know

Who is Funding the Study?
The Mayo Clinic Clinical Trials Anywhere as part of the Decentralized Clinical Trials (DCT) initiative is funding this 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 asked to wear the smartwatch and/or take metformin for up to 1 year. We would then like to follow your health for up to 2 years after you start this study. We will do so by calling you or sending you a portal message or email.

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

Before starting this study you will need to have the following tests to see if you are eligible:

- Medical history and physical exam
- Assessment of performance status (ability to do activities of daily living)
- Cognitive assessments (tests to check how your brain processes thoughts)
- Neurologic exam (tests to check your nervous system)
- Routine blood testing
- Pregnancy testing if you are able to become pregnant

There are two groups in this study:

- One group will receive a smartwatch and provide information from the smartwatch and complete questionnaires and visits for up to one year. This is the Control Group.
- The other group will receive a smartwatch and provide information from the smartwatch and complete questionnaires and visits for up to one year like the first group, plus they will be given the study drug, metformin, for up to one year. This is the Metformin Group.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the Metformin Group or the Control Group. Neither you nor the study doctor can choose your study group. You will have an equal chance of being assigned to the Metformin Group or the Control Group.

All patients who choose to take part in this study will be given a wearable device (also known as a “smartwatch”) to monitor your health data, including steps taken, exercise, calories burned, resting heart rate, heart rate variability, total sleep time, REM sleep time, and deep sleep time, sleep oxygen levels, and respiratory rate. You will get to keep this smartwatch after you complete the study.

You will need to register the smartwatch with the company that makes the smartwatch (Google FitBit). Smartwatches must be connected to your smartphone or computer to collect your health data.

To collect information about how you are doing, we will use an application ("app") from CareEvolution® called "MyDataHelps®." CareEvolution and MyDataHelps will not have access to your medical records. You will need to provide CareEvolution with your name, email address, telephone number, and mailing address to register and take part in this study. Mayo Clinic has hired CareEvolution to make gathering study data easier for study participants.

You may add the MyDataHelps app on your personal device (computer or smartphone). If you do not have a compatible device or do not want to use your personal device, a company called Validic, Inc., will provide you with a tablet if needed to complete this study. Mayo Clinic has hired Validic, Inc., to help manage these devices. The tablet can only be used to access MyDataHelps. You will need to return the tablet at the end of the study.

If you are randomized to the Metformin Group, you will receive metformin tablets to take by mouth twice a day for up to one year. You may take metformin with water at mealtime. You have the option to receive the initial supply at Mayo Clinic or have it shipped to you. The rest of your metformin may be shipped directly to you while you are in this study. You will need to reorder your metformin about every 3 months. You will also need to log when you take your metformin on your smartphone or tablet.

All patients will have visits with the study team every 3 months to collect data and see how you are doing. You may choose to have virtual visits by telephone, or video visits on your smartphone or computer, or in person visits at Mayo Clinic, whichever is most convenient for you.

At the end of 6 months and 12 months, we will arrange for you to get your blood drawn for routine testing at any Mayo Clinic location, or a laboratory near you, or in your home.

If you choose to have blood drawn in your home, we will use a service called Phleb-Finders. Mayo Clinic contracts with Phleb-Finders for drawing blood (also called "phlebotomy") when a patient can't come to Mayo Clinic. Phleb-Finders will be given information about you including your name, address, and telephone number, in order to draw your blood. Phleb-Finders will make the appointment directly with you. They will come to your home to draw your blood. And they will ensure the blood is processed so the results are available to you and your doctor.

Treatment and Post-Treatment Visits
All patients will have the following tests and procedures:

Prior to Day 1

- Pick up smartwatch or have it shipped to you (you may be able to get help with setup if needed)
- Pick up tablet or have it shipped to you to complete questionnaires (if needed)
- Complete baseline questionnaires on a smartphone or tablet
- If you are in the Metformin Group, you ~~will need~~ can decide whether to pick up your first metformin prescription at Mayo Clinic or have it shipped to you

Day 8

- Study team check-in (virtually or in-person) to see how you are doing and if everything is working okay

End of Month 1

- Study team check in (virtually or in-person)
- Health data transfer from the smartwatch (virtually)
- Complete questionnaires (virtually on smartphone or tablet)

End of Month 3

- Study team check in (virtually or in-person)
- Cognitive assessments (virtually or in-person)
- Neurologic exam (virtually or in-person)
- Questionnaires (virtually on a smartphone or tablet)
- Health data transfer from the smartwatch
- Metformin Group: Order prescription refill

End of Month 6

- Study team check in (virtually or in-person)
- Cognitive assessments (virtually or in-person)
- Neurologic exam (virtually or in-person)
- Questionnaires (virtually on a smartphone or tablet)
- Health data transfer from the smartwatch
- Routine blood testing at a Mayo Clinic location near you or in your home
- Metformin Group: Order prescription refill

End of Month 9

- Study team check in (virtually or in-person)
- Cognitive assessments (virtually or in-person)
- Neurologic exam (virtually or in-person)
- Questionnaires (virtually on a smartphone or tablet)
- Health data transfer from the smartwatch
- Metformin Group: Order prescription refill

End of Month 12

- Study team check in (virtually or in-person)
- Cognitive assessments (virtually or in-person)
- Neurologic exam (virtually or in-person)
- Questionnaires (virtually on a smartphone or tablet)
- Health data transfer from the smartwatch
- Routine blood testing at a Mayo Clinic location near you

End of study

- Study team check in (virtually or in-person)
- Cognitive assessments (virtually or in-person)
- Neurologic exam (virtually or in-person)
- Health data transfer from the smartwatch
- Return the tablet if one was loaned to you – packaging will be provided for you to send it back to Mayo Clinic
- Continue to enjoy your smartwatch!

For patients in the Metformin Group: You will have a follow-up visit about four weeks after you stop taking the study drug. This visit may be done virtually or in-person.

For all patients: After your last visit, you may be contacted by the study team during a clinic visit or by telephone or portal message or email every 3 months for a maximum of 2 years after you start this study.

During this study, you will be asked to answer questions about depression. If you have positive responses to these questions, the study team will refer you to appropriate mental health care providers. It is your choice to seek care from the providers you are referred to, to seek care from another provider or not to seek follow-up care. If you decide to follow up, any further medical testing and care 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.

Here is a table of what will happen and when in case it's easier to follow:

When	What will happen
Screening (in person or virtually)	• Medical history and physical exam • Cognitive assessments (tests to see how your brain processes thoughts) • Neurologic exam (tests to check your nervous system) • Routine blood tests. • Pregnancy testing if you are able to become pregnant
After you are enrolled in the study Prior to Day 1	• Pick up your new smartwatch or have it shipped to you (You may be able to get assistance with setting it up) • Pick up loaner electronic tablet or have one shipped to you to complete questionnaires (if needed) or get help programming your personal smartphone or tablet (if needed) • Complete baseline questionnaires on smartphone or tablet • If you are in the Metformin Group, you may pick up the first prescription or have it shipped to you
Day 1	• All Patients: Start tracking health if you haven't already done so • Metformin Group only: Begin taking metformin and tracking your doses on your phone or tablet
Day 8 (Virtual)	• Study team check-in
End of Month 1 (Virtual)	• Study team check in (virtually or in-person) • Health data transfer from the smartwatch (virtually) • Complete questionnaires virtually on smartphone or tablet • Metformin Group only: continue taking metformin and tracking your doses
End of Month 3 (Option for in-person or virtual)	• Study team check in (virtually or in-person) • Cognitive assessments • Neurologic exam • Health data transfer from the smartwatch • Metformin Group only: continue taking metformin and tracking your doses • Metformin Group only: order refill of metformin

When	What will happen
End of Month 6 (Option for in-person or virtual visit)	• Study team check in (virtually or in-person) • Cognitive assessments • Neurologic exam • Health data transfer from the smartwatch • Routine blood testing at a Mayo Clinic location or in your home • Metformin Group only: continue taking metformin and tracking your doses • Metformin Group: order refill of metformin
End of Month 9 (Option for in-person or virtual visit)	• Study team check in (virtually or in-person) • Cognitive assessments • Neurologic exam • Health data transfer from the smartwatch • Metformin Group only: continue taking metformin and tracking your doses • Metformin Group: order refill of metformin
End of Month 12 (Option for in-person or virtual visit)	• Study team check in (virtually or in-person) • Cognitive assessments • Neurologic exam • Health data transfer from the smartwatch • Routine blood testing at a Mayo Clinic location or in your home
End of treatment visit (Option for in-person or virtual visit)	• Study team check in (virtually or in-person) • Cognitive assessments • Neurologic exam • Health data transfer from the smartwatch • Return loaner tablet if you borrowed one from Mayo Clinic

Special Consideration

Since you are participating in mobile-device studies:

I am aware that nobody will be monitoring the data collected by the mobile devices (smartwatch, smartphone, or tablet) being used for this study, and I should not expect a response in the event that the device detects an irregular heart rhythm. I should monitor my own health as I ordinarily would and report any concerns about how I am feeling to my doctor or by calling emergency services (911) if needed.

I understand and agree with this statement:

☐ Yes ☐ No Please initial here: _____Date: _____

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

Side effects of metformin

Very Common: (>10%):

- Loose, frequent stools (diarrhea)
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Belly bloating (abdominal bloating)
- Passing gas (flatulence)

Common (1 to 10%):

- Stomachache (dyspepsia)
- Belly pain or swelling (abdominal pain or distention)
- Abnormal stool (may be discolored, different odor, looser or harder)
- Hard, infrequent stools (constipation)
- Heartburn
- Decreased levels of vitamin B12 in your blood – may feel tired
- Decreased levels of blood sugar (hypoglycemia) – may have rapid heartbeat, shaking, sweating, nervousness, dizziness, or hunger
- Weakness
- Muscle pain (myalgia)
- Headache
- Upper respiratory tract infection – may have coughing, runny or stuffy nose

Rare but serious effects (<1%):

- Lactic acidosis (a high acid level in the blood)
  Call your doctor right away if you have any of the following symptoms, which if new for you could be signs of lactic acidosis:
    - you feel abnormally cold in your hands or feet
    - you feel unusually dizzy or lightheaded
    - you have a slow or irregular heartbeat
    - you feel unusually very weak or tired
    - you have unusual muscle pain
    - you have trouble breathing that is new
    - you feel unusually sleepy or drowsy
    - you have new stomach pains, nausea, or vomiting

Most people adjust to taking metformin within a couple weeks. Tell your study team right away if you are having worrisome symptoms.

Risks from the Wearable Device (smartwatch)
There may be physical discomfort such as a rash from wearing the smartwatch. This risk is minor and usually goes away if you stop wearing the device for a little while. Tell your study team if you are unable to wear the device regularly.

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

Unforeseeable risks
Many side effects go away shortly after the study drugs are 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.

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. 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, others with cognitive effects from cranial radiation may benefit in the future from what we learn in this research study.

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

This study is only being done to gather information. You may choose not to take part in this study.

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

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Wearable device (smartwatch) to collect health data

- Loan of an electronic tablet if you need to borrow one for this study
- The study drug, metformin, if you are assigned to the metformin group
- In-home blood draws if you choose this option
- Glucose testing, if done at home or at Mayo Clinic for this study

You and/or your insurance will need to pay for all other tests and procedures that are part of this research study because they are needed for your clinical care including copayments and deductibles. These costs include:

- Cognitive assessments
- Neurological exams
- Routine blood draws and blood testing
- Pregnancy testing if you are able to become pregnant
- Glucose testing, if done at a non-Mayo Clinic site for this study

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. 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?

You won't be paid for taking part in this study. You can keep the smartwatch at the end of the study.

Will your information be used for future research?

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

We would like to keep your information for future research. You can still take part in this current study even if you don't want your information used for future research. Researchers at Mayo Clinic who aren't involved with this study may ask to use your information for future research. Researchers at other academic or medical institutions or companies may also ask for a part of your information 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 will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information by checking 'yes' below, Mayo Clinic may send the information to researchers who request them, but Mayo Clinic will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information 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.

Please read the following statements and mark your choices:

I permit my information to be stored and used in future research to learn about, prevent, or treat cancer at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

I permit my information to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat other health problems (for example, diabetes, heart disease, and Alzheimer's):

☐ Yes ☐ No Please initial here: _____Date: _____

I permit Mayo Clinic to give my information to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

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

Identifiers might be removed from the identifiable private information and after removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

How will your privacy and the confidentiality of your records be protected?

General Protections
Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Various methods are used to safeguard confidentiality. Some or all of the following may be used in this study: assigning a specific code or registration number to your data, research materials stored in locked areas, password protected data stored on a computer.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), 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.
- The wearable device ("smartwatch") provided for this study

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.
- Mayo Clinic, the sponsor of this study and the people or groups hired by Mayo Clinic 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.

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your Rights and Permissions

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

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

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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

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

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

Please be sure to include in your letter or email:

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

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

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