Autologous Adipose Derived Mesenchymal Stem Cells for Spinal Cord Injury Patients

NCT04520373

5/14/2026

MAYO CLINIC

Name and Clinic Number

Approval Date: **May 15, 2025**
Not to be used after: **May 14, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: CELLTOP Part 2: A Phase II Clinical Trial of Autologous Adipose Derived Mesenchymal Stem Cells in the Treatment of Paralysis due to Traumatic Spinal Cord Injury

IRB#: 19-011706

Principal Investigator: Mohamad Bydon, 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 observe the safety and efficacy of adipose derived- mesenchymal stem cells (AD-MSCs) for the treatment of severe, traumatic, spinal cord injuries. You have been asked to take part in this research because you have suffered from a spinal cord injury and your physician believes treatment with stem cells may benefit you.
What's Involved	Study participation involves approximately 8-9 visits to Mayo Clinic. Depending on treatment group, you will be enrolled in this study for approximately 24 – 30 months. If you agree to participate, you will be asked to maintain an occupational and physical therapy log; as well as, maintain a daily log of adverse events—these will be reviewed at your visits.

	You will visit with a broad range of healthcare professionals at each visit including neurosurgery, pain medicine and rehabilitation, and physical and occupational therapy. You will undergo a fat harvest to derive the stem cells that will be injected into your spine approximately 6-8 weeks post procedure.
Key Information	This study is randomized, meaning we will assign you by chance (like a coin toss) to Treatment Group 1 to receive stem cells or to Treatment Group 2, where you will be observed for 6 months prior to receiving stem cells. The risks associated with study participation are completely described later in this form, be sure to review them carefully. This study may not make your health better. However, the study agent may positively impact your pain, function, and/or quality of life.
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:** Mohamad Bydon, M.D. **Phone:** (507) 284-3331 **Study Team Contact:** Osha Grant **Phone:** (507) 293-7992 **Institution Name and Address:** Mayo Clinic 200 First Street, SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

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

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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 suffered from a severe, traumatic spinal cord injury causing paraplegia or tetraplegia.

The plan is to have about 40 people take part in this study at Mayo Clinic.

Why is this research study being done?

In this study, we want to find out more about the side effects of a new drug for spinal cord injuries, Adipose Derived-mesenchymal stem cells (AD-MSCs). Everyone in this study will receive AD-MSCs which is still 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 of the ways that this drug may affect people. This study isn't likely to help you, but we hope the information from this study will help us develop a better treatment for spinal cord injuries in the future.

Information you should know

Who is Funding the Study?
Dr. Bydon's Neuro-Informatics Laboratory at Mayo Clinic, Mayo Clinic and Minnesota Office of Higher Education are funding the study. These institutions will pay to cover costs related to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research, and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.
- Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

Depending on which treatment group you are randomized to, it will take you about 24-30 months to complete this research study. During this time, we will ask you to make 8-9 study visits to Mayo Clinic.

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

If you agree to be a part of this study, you will provide consent and participate in the following:

Screening Visit
During the Screening Visit, 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 aren't eligible, the Principal Investigator will tell you why.

At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart, and breathing rates)
- Draw a blood sample

- Ask you for a urine sample
- Test your [blood/urine] for pregnancy if you are a female able to become pregnant
- Give you some questionnaires to fill out about depression, bowel and bladder, and ask you to rate your pain on a numeric scale.

You will need to have the following exams, tests or procedures to find out if you can be in the study:

- Neurological and physical exam
- Somatosensory evoked potential (SSEP) testing
- Occupational and physical therapy evaluation
- Spine MRI

These exams, tests, or procedures are part of regular clinical care and may be done even if you do not join this study. If you had some of them recently, they may not need to be repeated. This will be up to the Principal Investigator.

Screening will be reassessed for Treatment Group 2 at Week 16

Randomization
If you are eligible for the study, we will assign you by chance (like a coin toss) to Treatment Group 1 to receive stem cells or to Treatment Group 2, where you will be observed for 6 months prior to receiving stem cells. You and the Principal Investigator can't choose your study group.

You will have an equal chance of being assigned to Treatment Group 1 or Group 2.

Treatment Group 1: AD-MSCs
Treatment Group 2: 6 months of observation followed by AD-MSCs

Treatment Group 2 Only

Best Medical Management Visits
Week 0, Week 16, and Week 24

At these visits, we will:

- Check your vital signs
- Ask you about side effects or health problems since your last visit
- Give you some questionnaires to fill out.
- Neurological and Physical Exam (if applicable)
- Occupational and Physical therapy evaluation (if applicable)

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Treatment Groups 1 & 2

Fat Harvest Visit
Treatment Group 1: Fat Harvest will take place after being deemed eligible after screening

Treatment Group 2: Week 18
At the Fat Harvest Visit we will:

- Check your vital signs
- Ask you about side effects or health problems since your last visit
- Fat biopsy from either your stomach or your thigh

A fat biopsy is done through a small (1-2 inch) cut in your abdomen or thigh, where approximately one tablespoon of fat is removed from under the skin. The actual site of the biopsy will be determined at the time of the biopsy. This procedure will be done by a certified registered nurse in the Clinical Research Translational Unit (CRTU) in the Charlton building. You will be given a local anesthetic to numb the site where the biopsy will be taken. The biopsy site will be closed using stitches that are absorbed by the body. The stitches are usually reabsorbed in one to three weeks. You will be given instructions on how to care for your biopsy site.

There is a possibility that the cells from the fat tissue removed during the biopsy may not grow. If this happens, a second biopsy will be done within four weeks of the initial biopsy. If the second biopsy sample does not grow cells, no further biopsies will be done, and you will not continue as a participant in the study.

Injection Visit

Treatment Group 1: Week 0
Treatment Group 2: Week 24
If you qualify to continue in the study, you will return to clinic approximately 6 to 8 weeks after the fat harvest visit in order to receive the stem cell injection.

At this visit, you will:

<u>Prior to injection</u>

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart, and breathing rates)
- Draw a blood sample
- Occupational and physical therapy evaluations

During Injection

- A cerebral spinal fluid (CSF) sample will be taken prior to the injection
- A blood sample (approximately 1 tablespoon) may also be taken for research purposes if you agree below
- Injection of AD-MSCs into the intrathecal space of the spinal cord under x-ray guidance

After the injection, you will have your blood pressure, heart rate, temperature, and breathing measured every 15 minutes for one hour, then every hour for four hours, then every four hours until you are discharged. You will be observed for seizures and a neurological exam will be performed the morning after the study injection, before you are sent home.

You will be admitted the day of the procedure to the in-patient Clinical Research Translational Unit (CRTU) at Saint Mary's hospital and will stay there overnight. You may have supper the evening prior to the procedure.

Two hours after the injection, you will be able to get out of bed, sit in a chair, move around, and eat regular food for the rest of your stay. It is advisable that you have someone available to assist with your transport back to your home the next morning. In some cases, pain from the injection can persist for up to 1 week. There may be some localized pain from passing the needle. You can also take your regular medications.

When you are sent home, you will be given a set of instructions telling you what you may and may not do. You are to call the study doctor immediately if you experience increased pain, swelling, redness, fever, or drainage (fluid leaking) from the injection site.

At the time of discharge from the CRTU, you will be provided phone numbers and instructions should you need to contact the study team with any questions or concerns.

Post-Injection Follow-Up Visits

Treatment Group 1 Visits: Weeks 1, 4, 24, 48, 96
Treatment Group 2 Visits: Weeks 25, 28, 48, 72, 120
At these visits, we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart, and breathing rates)
- Physical and Neurological exams by a physician
- Occupational and physical therapy evaluations – if applicable
- Somatosensory evoked potentials (SSEPs) – if applicable
- Spine MRI – if applicable

Treatment Group 1 Visit: Week 12
Treatment Group 2 Visit: Week 36
This visit will be conducted virtually. We will:

- Review your current medications
- Document any potential adverse events since your last visit
- Provide a copy of the questionnaires for you to fill out and send back

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?

Risks Associated with Fat Biopsy
The fat biopsy is usually well tolerated; however, there can be some discomfort with the injection of the anesthetic, discomfort after the procedure is done, bruising, pain and swelling and rarely infection at the biopsy site.

Risks Associated with Stem Cell Products
The risks of injection of mesenchymal stem cells into the cerebrospinal fluid are unknown. They may include getting weaker, sensory loss (for example numbness), pain, and even death. Like any therapeutic agent, allergic reactions are a possibility. In one recent study, 19 patients with ALS were injected with MSCs in a manner similar to that described in this study. Of these 19 patients, 11 patients had mild fevers and 5 developed headache, 2 developed leg pain, and 1 had shortness of breath. One subject in a Mayo Clinic trial had thickening of the nerve roots in the back that was asymptomatic. It is unclear whether these symptoms were related to the MSC treatment.

<u>Potential Cell Contamination</u>
The stem cells could become contaminated, which could cause you to develop an infection. This risk is greatly decreased by the use of a production facility that follows a set of standards called Good Manufacturing Practice (GMP) that are accepted by the government health agencies. Before the stem cells are released from the manufacturing facility, screening tests for a number of agents that can cause infection are performed. As with any blood or marrow-derived product, infectious risks from unknown pathogens are possible.

Potential Inflammatory Responses
Stem cells may cause inflammation. While possible, this response has not been seen in human or animal studies involving intrathecal injection of stem cells. You will be monitored for these responses with blood inflammatory marker tests at follow-up study visits, as well as with repeat cerebrospinal fluid analysis at a follow-up study visit.

Potential Risk of Tumor
Stem cells are living cells and there is a risk that these cells could directly or indirectly cause unwanted tissue growth or a tumor. Mesenchymal stem cells (MSCs) have been tested in animals and humans to see if they cause unwanted tissue growth or tumors. So far, no unwanted tissue growth or tumor has been seen in human studies or in any other animal study with MSCs.

Risks Associated with Magnetic Resonance Imaging (MRI) Scanning
There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped. The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

Risks Associated with Fluoroscopy
You will be exposed to additional x-ray radiation during this research study. The amount of radiation you will receive has a low risk of harmful effects.

Risks Associated with Blood Tests
You will have blood taken for this study to assess your health. Blood samples will be taken from a vein in your arm during the study. Taking a blood sample may cause some temporary discomfort and other side effects such as the following: fainting, redness, pain, bruises, bleeding and/or infection. If you feel faint, tell the study staff right away.

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing will include whole genome sequencing (mapping your entire genetic code). Whole genome sequencing generates a large amount of information that may provide, now or in the future, important insights into your health as well as the health of your biologic family members.

If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of

choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family.

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.

Pregnancy

This research study may involve risks to you or your unborn child, which are currently not known. If you are a woman, you must not get pregnant for 24 months after injection. The only way to not get pregnant is to not have sex. If you are a woman who is able to have children and choose to have sex, you must use a type of birth control listed below.

Methods of birth control for this study include:

- Abstinence (not having sex)
- Hormonal (examples are birth control pills or patches, progestin implant or injection)
- Barrier method (examples are diaphragm with spermicide, intrauterine device (IUD), condom and foam)

Even if you use birth control during the study, there is a chance you could become pregnant.

You cannot enter into the study if you are pregnant or breast-feeding. If you become pregnant after having received the study injection, no further MRIs will be obtained during the study. The procedure and study injection, or the tests that need to be done, may have unknown risks to breast-fed babies.

You must inform your study doctor immediately if you think you may be pregnant. You will continue to be monitored for the remainder of the 24 months of duration of follow-up for the study.

Possible Effects on Fetus
Because of potential or unknown side effects of the study on the fetus, if you are a woman able to have children, you must have a negative blood pregnancy test before entering the study as well as a negative urine pregnancy test immediately before injection on the day of the injection. Women who are able to have children will be allowed to participate in this study provided that they agree to use adequate contraception (hormonal or barrier method or abstinence) from the time of screening and for a period of at least 24 months after injection.

Additional Costs
Taking part in this research study may lead to added costs to you. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance company to see what services will be covered and what you will be responsible to pay.

Risk summary
Many side effects go away shortly after the injection 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.

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

Are there reasons you might leave this research study early?

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

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

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

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

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

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

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. 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, the study agent may positively impact your pain, function, and/or quality of life.

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 but are not limited to surgery, comprehensive inpatient rehabilitation, comprehensive outpatient medical management, and outpatient physical therapy and occupational therapy. Your participation in this study can be done in addition to these other treatment options. You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

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

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

- Research blood tests being performed for the study
- Lumbar puncture studies
- Observation at the CRTU following the procedure
- Fluoroscopy guided injection with the mesenchymal stem cells
- Fat Biopsies
- Study visits, including examination and history done as part of each study visit
- Physical and occupational therapy evaluations
- Questionnaires
- MRI of the spine

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular clinical care.

These tests and procedures are:

- Full Spine MRI at screening.

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

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

You will not be paid for taking part in this study.

Will your information or samples be used for future research?

As part of this study, there will be the option of having a sample of your cerebrospinal fluid and blood stored for future studies about the immune system and to learn about, prevent, or treat other health problems. You can still take part in the main study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

If you agree, a portion of the blood (approximately ½ tablespoon) taken during the following visits, screen visit, and post-injection week-0, week-1, and week-2 that are part of the main study will be sent to the lab and stored.

If you agree, a portion of the cerebrospinal fluid (approximately ¼ teaspoon) taken during the following visits, day of the stem cell injection procedure and 4-weeks post injection, that are part of the main study will also be sent to the lab and stored.

Because this is not part of regular medical care, you will not be told the results and the test results will not be put into your medical record. Mayo Clinic may destroy the sample at any time without telling you.

I permit my samples to be stored and used in future research about the immune system and to learn about, prevent, or treat other health problems at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

It is not considered a risk factor to die during the study, but we ask that you consider donating your body to an autopsy, if you should die during the period of your participation of the study.

I permit an autopsy by Mayo Clinic if I should die during the study:

☐ Yes ☐ No Please initial here: _____Date: _____

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

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

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. Study file information will be stored in locked file cabinets in a secure location that can only be accessed by cardkey access. All electronic information will be stored in a username and password protected computer on a Mayo Clinic server. Data about the cell acquisition, characterization and release criteria will be maintained by Immune, Progenitor, and Cell Therapeutics (IMPACT) at Mayo Clinic using standard procedures.

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.

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

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

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

Please be sure to include in your letter or email:

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

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

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

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Enrollment and Permission Signatures

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

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Witness signing for participant, if applicable: I observed the entire consent conversation and confirm that the participant appears to understand the information and was given the opportunity to ask questions. Please sign your signature on behalf of the subject.

Witness Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Witness 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