Consent Form (includes HIPAA Authorization)

Title of Research Study: Brivaracetam to Reduce Neuropathic Pain in Chronic SCI: A Pilot Clinical Trial

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

University of Minnesota, Minneapolis	
Investigator Name: Dr. Leslie Morse, DO Investigator Departmental Affiliation: Chair, Department of Rehabilitation Medicine, University of Minnesota Phone Number: 612-626-5957 Email Address: morsel@umn.edu	Rehab Lab Study Staff Phone Number: 612-301-3072 Email Address: rehablab@umn.edu

Supported By: This research is supported by the Craig H. Neilsen Foundation. This trial is registered at the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov (NCT04379011).

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Co-Investigator Scott Falci, MD, has a patent application submitted for the use of Briviact in spinal cord injury neuropathic pain.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to

provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have had a spinal cord injury and have severe nerve pain.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- We will inform you if new information becomes available, including any new neuropathic pain treatments that might affect your decision to participate in this study.

Why is this research being done?

Spinal cord injury can be associated with severe nerve pain that doesn't respond well to treatments. In this study, we want to see if treatment with a drug called Brivaracetam can safely help control pain in patients with spinal cord injury. Brivaracetam is FDA-approved to treat epilepsy but is experimental when used for nerve pain associated with spinal cord injury. We also want to see what changes take place in your mood, brain, and genes when you take this drug, to help us design more research with this drug in the future.

How long will the research last?

We expect that you will be in this research study for about 4 months.

What will I need to do to participate?

You will be asked to provide blood samples, have two MRIs, fill out surveys, and take Brivaracetam or placebo (sugar pill) as instructed by the study team. The study medication dose will be increased over the first 4 weeks of the study to a maximum dose of 100mg twice a day (morning and night).

- For the first 2 weeks, we will ask you to take 50mg twice a day.
- If you tolerate this well, we will ask you to increase the dose to 50mg three times a day for 2 weeks.
- If you tolerate this well, we will then ask you to increase the dose to 100mg twice a day for the rest of the study.

If at any point you do not tolerate the drug, we will ask you to reduce the dose to the last step that you tolerated well without symptoms.

If you have an implanted medical device (such as a baclofen pump, spinal cord stimulator or

pacemaker), you may still be eligible for the study, but will not receive MRI scans.

If you do not wish to have an MRI, you may still be eligible for the study, but will not receive MRI scans.

If you do not wish to participate in baseline and end-of-study biomarker blood draws, you may still be eligible for the study, but will not take part in the blood banking.

You will be required to complete an end-of-study blood draw to evaluate your liver function for safety.

If you live out-of-area or are unable to travel to the University of Minnesota campus, you may still participate in the study. Your research appointments will be completed over the phone or zoom and you will complete the two required blood draws with your regular primary care provider who will then send us the results. You will not be able to take part in the MRI scans or optional blood banking activity.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

There are some potential risks to participating in this study, but we will minimize those risks as much as possible.

Risk of Brivaracetam Use:

Taking Brivaracetam may cause side effects.

Common side effects are those experienced by at least 5% of adults taking Brivaracetam. These include: nausea/vomiting, somnolence/sedation, dizziness, fatigue.

Rarer side effects are experienced by less than 5% of adults taking Brivaracetam. These include:

- suicidal behavior or thoughts of self-harm
- excess sleepiness
- psychotic symptoms (such as hearing voices, feeling paranoid, or feeling agitated)
- irritability or changes in mood
- loss of coordination or balance
- constipation

If you experience any of these symptoms, please let us know. We may recommend that you reduce the dose of medication that you are taking. Many times this eliminates the symptoms. For instance, if you feel excessive sleepiness at 100mg twice a day (maximum study dose), we may recommend that you reduce the dose to 50mg three times a day.

Other rare but serious side effects also include:

- allergic reaction (shortness of breath, rash, swelling)
- seizure when stopped abruptly without tapering

You should stop using Brivaracetam and contact the study team at once if you have any of these serious side effects or allergic reactions (shortness of breath, rash, swelling) or thoughts of suicide or self-harm.

The following medications that are not safe to take while you take Brivaracetam: rifampin, carbamazepine, buprenorphine, propoxyphene, levetiracetam, sodium oxybate, or phenytoin. You are not eligible to participate in this study if you are taking one of these drugs. You should let us know if you are considering starting one of these drugs so that we can safely stop Brivaracetam and remove you from the study.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section.***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a reduction in your nerve pain.

What happens if I do not want to be in this research?

You do not have to participate in this research. Instead of being in this research study, you may continue to receive your usual care for pain from your doctor. This may include any pain medications or treatments that your doctor may recommend for your nerve pain.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 20 people will complete this research study at our 2 enrollment sites (Swedish Medical Center/Craig Hospital and University of Minnesota). We expect about 40 people will complete the research study overall.

What happens if I say "*Yes, I want to be in this research*"?

If you decide you want to be in this research study, you will have 4 in-person study visits over four months. If you prefer, Visit 1 and Visit 2 can be combined for your convenience. You can expect the following procedures during your study visits listed below. We may complete testing over a series of visits at each time point if this is more convenient for you.

Obtain Medical Clearance

Before you can start the study, you will need to see your primary care physician (your regular doctor) to obtain medical clearance. This visit must occur within one month of Visit 1. Your doctor will complete a physical exam, a health history, and collect 3-4 tablespoons of blood to confirm that you are not pregnant (for people of childbearing potential) and that your kidneys and liver function properly. Your

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insurance will be charged for this visit and you will be responsible for any associated copays or costs, including any amount not covered by your insurance. We can provide you with a list of the required labs and we recommend that you contact your insurance in advance to see if you will have any costs associated with these tests.

If you are an M Health Fairview patient, we will pull the results directly from your electronic health record. If your doctor is not part of the M Health Fairview care system, we will ask that you or your doctor provide research staff with the results.

Visit 1

At your first study visit, the study will be explained to you, and you will be given a chance to ask questions. A member of the study team will review the consent form with you. After you have enrolled in the study we will assign you randomly to one of 2 groups: the group that receives the active drug (Brivaracetam) or the group that receives a placebo (sugar pill). There is a 50-50 chance that you will be assigned to one group or the other, similar to flipping a coin. We will give you instructions on how to take the study drug and a drug diary for you to record your study drug use, your daily pain ratings, and any additional medications you may be taking.

Additionally, once a week a member of our research team will call to ask you about any side effects you may be experiencing while taking the study drug. This team member will not know if you are taking active drug or the placebo (sugar pill). You can complete this call via phone or Zoom.

Visit 2

At this visit:

- You will have a Magnetic Resonance Imaging (MRI) scan of your brain. This activity is described in the section titled "**MRI Scan**" below.
- You will fill out some surveys relating to pain, mood, satisfaction with life, and community integration.
- If you choose to participate in the optional blood banking, we will collect about 3-4 tablespoons of blood for research purposes. We will study potential biomarkers of pain in SCI, including microRNAs. MicroRNAs are small nucleic acids that control various cellular processes and may be involved in the production of pain. We are not doing genetic analyses in this study.
- You will have a physical exam and answer health questions.
- RxArtisans Pharmacy will FedEx the drug to you and study staff will send an email notification that the drug has been sent by overnight mail.

Visit 3

This visit will take place about 3 months after Visit 2. This is your final study visit. At this visit:

- You will have a second MRI. This activity is described in the section titled "**MRI Scan**" below.
- You will fill out some surveys relating to pain, mood, satisfaction with life, and community integration.
- If you choose to participate in the optional blood banking, we will collect about 3-4 tablespoons of blood for research purposes. We will study potential biomarkers of pain in SCI, including

microRNAs. MicroRNAs are small nucleic acids that control various cellular processes and may be involved in the production of pain. We are not doing genetic analyses in this study.

- You will have a physical exam and answer health questions.
- You will have a fasting blood draw to assess your organ health. You have two options for this: you can either have your blood drawn at the Clinical Research Unit on the University of Minnesota campus OR you can return to your primary care provider (your regular doctor) to have your blood drawn and your doctor's office will send us the test results. It is important for you to be aware that if you complete this activity with your own provider, your insurance will be charged for this visit and you will be responsible for any associated copays or costs, including any amount not covered by your insurance. If you choose to go this route, we recommend that you contact your insurance provider in advance so that you can know what to expect. If you complete your blood draw at the University of Minnesota research site, your blood draw and labs will be paid for by the study; there will be no cost to you.
- If you are of child-bearing potential, you will complete a urine pregnancy test.

Visit 4

- You will fill out some surveys relating to pain, mood, satisfaction with life, and community integration.

2 weeks dose reduction after end of study testing

- Someone from the study will call you to remind you to start reducing the dose of the study drug so that you can safely stop taking it when the study ends. You will be instructed to take 1 pill twice a day for one week and then 1 pill once a day for 1 week and then stop taking it entirely.
- You will be asked to mail empty bottles to RxArtisans Pharmacy for pill counts with self-addressed, prepaid packaging we will provide for you.

MRI Scan:

(In-person participants only)

If you agree to take part in the MRI scans and we have determined that an MRI scan will be safe for you (no contraindications to MRI), you will have a scan at Visit 2 and again at Visit 3. These visits will take place at the Center for Magnetic Resonance Research located on the East Bank of campus.

In order to ensure your safety, we may ask you to undergo some additional safety screening measures such as a pregnancy test, x-ray, and completing a safety questionnaire. Additional information about MRI risks and safety measures can be found in the section titled "**Risk of MRI Scans**" below.

Prior to your MRI scan, we will ask you to remove any jewelry and removable metallic objects from your body. We will provide you with a pair of hospital scrubs to wear during your scan.

The scanner is a very large tunnel. You will lie on your back on a narrow table that will slide you into the tunnel. We may ask you to imagine yourself performing tasks with your legs, such as walking or standing, or finger tapping for a few moments while you lie still during the MRI scan.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- attending all study visits
- taking study medication as instructed
- telling the study team about any side effects that you experience

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you decide to leave the research study, tell the study team about your decision. We may ask you to complete some evaluations at a final study visit.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

In addition to the risks of Brivaracetam described above, risks in this study include:

Risk of MRI Scans:

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or Computed Tomography (CT) scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to deoxyribonucleic acid or DNA) like x-rays or CT scans. The risks associated with MRI scans are:

- *Projectiles*: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.
- *Claustrophobia*: The scanner is a long narrow tube that may cause some people to feel claustrophobic.
- *Hearing Damage*: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.
- *Nerve Stimulation*: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.
- *Disruption of Devices*: Some devices can be damaged by magnetic fields and should not be

brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.

- *Heating of Devices*: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the scanning operator and should notify the operator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

Risk of Blood Draws:
The risk of infection during blood draw is low because we clean the skin first and use sterile techniques. There is a risk of pain and bruising. If this occurs, we expect it to be mild and to resolve in a day or two. Sometimes people feel faint or lightheaded during a blood draw.

Risk of Loss of Confidentiality:
There is a small risk that your confidential medical information could be revealed or discovered by mistake. Information about you taking part in this study or the results of the research won't be placed in your medical records. In addition, your samples and information will be coded and the key to the code will be kept in a separate, locked file. We won't share or publish any information that will identify you. There is also a small chance that, if you engage in a videoconference through the Zoom for Healthcare platform, the Zoom session could be hacked.

Will I receive any imaging results after an MRI?

The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your pictures. The investigator in charge of this study will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your own physician. However, further medical follow up is not a part of this study and the study does not have funds set

aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

Will I know about any new information about the effects of MRIs on human health?

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

Prior to enrolling in the study, we ask that you see your primary care physician to determine if you are eligible, including having your physician order lab work to confirm that you are not pregnant (for people of childbearing potential) and that your kidneys and liver function properly. Your insurance will be charged for that visit and you may be responsible for any associated copays or costs. If your insurance does not cover this visit with your primary care provider and the associated lab work, you will be required to pay any uncovered amount out of pocket, up to the full cost of the visit. We recommend that you check with your insurance and your provider before scheduling your visit.

The study drug, lab costs, physical examinations and MRIs performed for this study will be paid for by the study.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed for a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information". In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share health information for research and why they may need to do so.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form. If you sign this

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Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.
Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside of the UMN, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

What health information will be made available?
Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?
Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)
☐ My HIV/AIDS testing records _____ (initial)
☐ My genetic testing records _____ (initial)
☐ My mental health diagnosis/treatment records ____ (initial)
☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?
If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us.

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- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others); Department of Rehabilitation Medicine staff or UMN Clinical Research Unit staff involved in this study; Non-research staff at the Department of Rehabilitation Medicine or UMN Clinical Research Unit who need this information to do their jobs (such as for billing, or health care operations).
- The Craig H. Neilsen Foundation (the sponsor of this study), and the people or groups it hires to help perform this research, as well as any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research.
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and a group that oversees the data (study information) and safety of this research.
- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.
- In the instance that you engage in a study-related videoconference through the Zoom video-conferencing platform, Zoom does not have access to identifiable protected health information (PHI) and they protect and encrypt all audio, video, and screen sharing data. These Zoom sessions will not be recorded or maintained.
- People from organizations that provide independent accreditation and oversight of hospitals and research.
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers.
- 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 US or foreign government bodies that oversee or review research).
- Public health and safety authorities (for example, if we learn information that could mean harm to you, we may need to report this, as required by law).

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or

- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of the UMN. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or identifying information **will not** be used for these purposes without your specific permission.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?
No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?
No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?
Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

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What happens to my health information after it is shared with others?
When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?
It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

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

Will I receive research test results?

NO Results will be shared
Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

You can call us with your questions or concerns. Ask questions as often as you want. You can call us at 612-301-3072, Monday through Friday, 8am-4:30pm or email at rehablab@umn.edu. Leslie Morse, DO is the person in charge of this study. You can call her 612-626-5957 Monday through Friday 9am-5pm.

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant.

You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $350 for your time, effort, and to assist with transportation. You will receive $150 after Visit 2, $150 after Visit 3 and $50 after Visit 4.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Consent Form (includes HIPAA Authorization)

Optional Elements:

MRI scans
In-person participants only
If you do not have any contraindications to MRI and you are able, do you agree to take part in the research MRIs?

☐ Yes ☐ No ☐ N/A Participant Initials: _____

Interest in blood sample banking
In-person participants only
Three to four tablespoons of blood samples will be collected in and stored locally in a -80 freezer at UMN. Blood samples will be labeled by ID number, type (plasma or serum), and date of draw. If you are able, do you agree to let us store your blood samples and health information for future research related to nerve pain and spinal cord injury?

☐ Yes ☐ No ☐ N/A Participant Initials: _____

Interest in future research

I would like to be contacted about future research studies that may interest me.

Participant Initials: _____

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Consent Form (includes HIPAA Authorization)

For the Consent of Non-English Speaking Participants when an Interpreter is Used:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual

Witness to Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated their consent and authorization for participation by (check one box as applicable):

☐ Making their mark above

☐ Thumb print _____

_____
Witness Print Name Date/Time