INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) / "Brivaracetam to Reduce Neuropathic Pain in Chronic SCI: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial"**
Protocol Number:	**STUDY00015302**
Principal Investigator: (Study Doctor)	**Ricardo Battaglino, PhD**
Telephone:	**612-625-2661 (24-Hours)**
Address:	**University of Minnesota Department of Rehabilitation Medicine** **420 Delaware Street SE** **MMC 297** **Minneapolis, MN 55455**

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 (Brivaracetam) in spinal cord injury neuropathic pain. As a result, the investigator may benefit financially from a successful study. Additional steps have been taken to manage the potential conflict of interest that this arrangement may create. Please speak with your study doctor if you have questions about this.

KEY INFORMATION

You are invited to take part in a research study. This research study is studying Brivaracetam as a possible treatment for severe nerve pain among individuals with spinal cord injury (SCI). The National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) is sponsoring this research study.

- 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 study drug called Brivaracetam can safely help control pain in patients with spinal cord injury.
- Brivaracetam is approved by the United States Food and Drug Administration (FDA) 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 study drug, to help us design more research with this drug in the future.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE
You are being asked to participate in this research study because you have a spinal cord injury.

The purpose of this research study is to:
- Test the efficacy of the study drug, Brivaracetam, to reduce nerve pain in SCI.
- Determine whether Brivaracetam impacts mood, brain, and genes to help us design more research with this study drug in the future.

Brivaracetam is FDA- approved to treat epilepsy but is experimental when used for nerve pain associated with spinal cord injury. Brivaracetam in this study is investigational. An investigational use is one that is not approved by FDA.

Up to 48 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?
Your participation in this study will last approximately 11 weeks and will include 3 study visits to the study site; however, depending on your preference, participation in the study can also be entirely virtual which would require no visits to the study site.

If you decide you want to be in this research study, you will have 3 in-person or virtual study visits over 11 weeks. 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.

Study Treatment:

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 about 2-3 tablespoons of blood 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 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 your doctor is a part of our system of care, we will pull the results directly from your electronic health record. If your doctor is not part of our system of care system, we will ask that you or your doctor provide study 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 staff 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 study 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. This is a double-blind study, which means neither you nor the study doctor or study staff will know to which of these study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.
- 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.
- You will fill out some surveys relating to pain, mood, satisfaction with life, community integration, fear of movement related to pain, and sleep.
- You will have a physical exam (including a neurological exam, if in-person) and answer health questions.

Visit 2

This visit may be combined with visit 1.

- An optional Magnetic Resonance Imaging (MRI) scan of your brain. This activity is described in the section titled “MRI Scan” below (in-person only).
- An optional blood banking where we will collect about 3-4 tablespoons of blood for research purposes (in-person only). We will study potential biomarkers (molecules that may be a sign of a condition or disease) of pain in SCI, including microRNAs. MicroRNAs are small molecules that control various cellular processes and may be involved in the production of pain. We are not doing genetic analyses in this study.
- If in-person, the 7-week supply of the study drug will be dispensed to you. If virtual, the study drug will be mailed to you.

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

Visit 3

This visit will take place about 6 weeks after Visit 2. This is your final study visit. At this visit:

- You will fill out some surveys relating to pain, mood, satisfaction with life, community integration, fear of movement related to pain, and sleep.
- You will have a physical exam (including a neurological exam, if in-person) and answer health questions.
- You will have a fasting blood draw (about 2-3 tablespoons) to assess your organ health. You have two options for this:
    - You can either have your blood drawn at the study site
      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 study 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.
- You will have a second optional MRI. This activity is described in the section titled "MRI Scan" below (in-person only).
- 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 molecules that control various cellular processes and may be involved in the production of pain. We are not doing genetic analyses in this study.

After Study Treatment:

2 week 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 the pill bottles, any remaining pills, and your study drug diary with a self-addressed, prepaid packaging we will provide for you.
- Since this is a research study, the study drug will be given to you only during this study and not after the study is over.

The final study visit (Visit 4) will occur one month after stopping the study drug. A member of our study staff will call to ask you about any side effects you may be experiencing, your pain

level, medications, and they will administer surveys related to mood, satisfaction with life, community integration, fear of movement related to pain, and sleep. You can complete this call via phone or Zoom.

MRI Scan:
(In-person subjects only)
If you agree to take part in the MRI scans and we have determined that an MRI scan will be safe for you, 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.

EXPECTATIONS
If you participate in this study, you will be expected to:
- Attend all study visits
- Take study drug as instructed
- Tell the study staff about any side effects that you experience

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Risk of Brivaracetam Use:
Taking Brivaracetam may cause side effects. Common side effects are those experienced by at least 5% (5 or more out of 100) of adults taking Brivaracetam. These include:
- Nausea
- Vomiting
- Somnolence (drowsiness)
- Sedation (sleepiness)
- Dizziness
- Fatigue (tiredness)

Rarer side effects are experienced by less than 5% (5 or less out of 100) 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/changes in bowel

If you experience any of these symptoms, please let us know. We may recommend that you reduce the dose of study drug 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:

- Seizure when the study drug is stopped abruptly instead of decreasing the study drug slowly.
- Allergic reaction - Some symptoms of allergic reactions are:
    - Rash
    - Wheezing and difficulty breathing
    - Dizziness and fainting
    - Swelling around the mouth, throat or eyes
    - A fast pulse
    - Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

You should stop using Brivaracetam and contact the study staff at the telephone number listed on the first page of this form at once if you have thoughts of suicide or self-harm.

If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).

The following medications **are not safe to take** while you take the study drug Brivaracetam:

- Rifampin
- Carbamazepine
- Buprenorphine
- Propoxyphene
- Levetiracetam
- Sodium oxybate
- Phenytoin

You are not eligible to participate in this study if you are taking any 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.

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, which is high-energy radiation that can potentially cause damage to deoxyribonucleic acid (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 study doctor.
- **Nerve Stimulation:** Some people experience tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the study doctor.
- **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 study doctor.
- **Heating of Devices:** The radiofrequency waves used in MRI can heat 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 study doctor or study staff 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.

RISKS OF STUDY PROCEDURES
Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

You may have difficulty swallowing the pill due to its size, and the pill cannot be crushed to make it easier to swallow. If you are unable to swallow the pill, notify the study coordinator to discuss possible alternative solutions (e.g., discontinuing participation in the study, or obtaining smaller pills from the pharmacy if available).

If you receive placebo (sugar pill) as part of this study, your symptoms of nerve pain may not improve or may get worse.

UNFORESEEN RISKS
Since the use of the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

BIRTH CONTROL RESTRICTIONS
Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

Females:
In order to reduce the risk of pregnancy, you should currently be using two effective forms of birth control while you are participating in this study (defined as those, alone or in combination, that result in a low failure rate, less than 1% per year (1 out of 100) when used consistently and correctly). The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study, tell your study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended.

ALTERNATIVES TO PARTICIPATION
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.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS
You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION
You will be paid up to a total of $350 if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $150 following Visit 2.
- $150 following Visit 3.
- $50 following Visit 4.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete. You will be paid following each completed visit.

If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal,

administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

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. You may be responsible for any associated copays or costs, including any amount not covered by your insurance. 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.

The study drug, *in-person* study-related procedures, and *in-person* study visits will be provided at no charge to you or your insurance company. If you choose to participate virtually, your

insurance will be charged for the required safety labs associated with Visit 3 and you will be responsible for any associated copays or costs, including any amount not covered by your insurance.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

FUTURE RESEARCH STUDIES
Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another study doctor for future research studies without additional informed consent.

COMMERCIAL PROFIT
Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) **and you will not share in this profit.**

CLINICALLY RELEVANT RESULTS
Research results that are clinically relevant, including individual research results, **will be disclosed to you** under these conditions:

- When the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, the study doctor will attempt to notify you. You and your clinical care person(s) are responsible for further evaluation/follow-up in response the findings.
- If results from the MRI 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 study doctor 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.

GENOME SEQUENCING
Researchers can look closely at large amounts of your genetic information by sequencing, or “reading,” every letter in your DNA (your genome). Reading a person’s entire genetic code is called whole genome sequencing. The research **might include** future whole genome sequencing but will not be used for clinical diagnosis and will not have any clinical utility.

Genetic Information Nondiscrimination Act (GINA)-US:

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 the sponsor will 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 that the sponsor will get from this research 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 and all employers with 15 or more people must follow this law.

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

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and to assume that you are on the study drug. Bring the medication bottle with you to the hospital and call the study coordinator at (651) 353-7690 or the study PI at (617) 365-3694 (phone number also listed on the medication bottle). The treating physician may reach out for more information about the study drug.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00061782.

CONSENT ELEMENTS

The following research activities are optional. Your decision will have no impact on your ability to participate in the main study and will have no impact on any other benefits to which you would otherwise be entitled.

Please indicate your willingness to participate in these optional activities by placing your initials, mark, or thumbprint next to each activity.

MRI Scans

(In-person subjects only)

If you qualify for an MRI, do you agree to take part in the research MRIs as described above in the **MRI Scans** section?

Please indicate your preference below:

☐ **YES _____(initials/mark/thumbprint)** I agree to participate in MRIs as described in the **MRI Scans** section above.

☐ **NO _____ (initials/mark/thumbprint)** I do not agree to participate in MRIs as described in the **MRI Scans** section above.

Blood sample banking

(In-person subjects only)

Three to four tablespoons of blood samples will be collected and stored locally in a -80° freezer at the University of Minnesota. 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?

Please indicate your preference below:

☐ **YES _____(initials/mark/thumbprint)** I agree to participate in the blood sample banking as described above.

☐ **NO _____ (initials/mark/thumbprint)** I do not agree to participate in the blood sample banking as described above.

Contacted for future research

I would like to be contacted about future research studies that may interest me.
Please indicate your preference below:

☐ **YES _____(initials/mark/thumbprint)** I agree to be contacted for future research.

☐ **NO _____ (initials/mark/thumbprint)** I do not agree to be contacted for future research.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- Intolerant to a required study procedure
- Failure to adhere to study requirements
- Positive hGC for individuals of childbearing potential
- Experience of a serious adverse experience
- Development of an illness that would, in the judgment of the study doctor, affect assessments of clinical status to a significant degree
- Enrollment in another investigational study

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

WITNESS SIGNATURE FOR SUBJECTS WHO ARE PHYSICALLY UNABLE TO TALK OR WRITE

The study subject has indicated that he/she is unable to read, write, or are physically unable to talk or write. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff. The subject has indicated his/her consent and authorization by (check one box as applicable):

☐ Making his/her mark above
☐ Thumb print

_____ _____

Name Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- The study doctor and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research.
- Representatives of National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.
- Organizations that process any payments that may be made to you for participating in this study.

- 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.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe.
- For other research activities related to the study.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

WITNESS SIGNATURE FOR SUBJECTS WHO ARE PHYSICALLY UNABLE TO TALK OR WRITE

The study subject has indicated that he/she is unable to read, write, or are physically unable to talk or write. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff. The subject has indicated his/her consent and authorization by (check one box as applicable):

☐ Making his/her mark above
☐ Thumb print

_____ _____

Name Date