COVER SHEET

Official Title: Optimizing Impact of Manual Therapy and Exercise on Lumbar Spinal Stenosis with Neurogenic Claudication: A Multi-Site Feasibility Study

ClinicalTrials.gov ID (NCT number): NCT06023498

Document Date: 01/14/2025

Participant Name: _____ IRBNet ID: **1784627**

Title of Study: Optimizing Impact of Manual Therapy and Exercise on Lumbar Spinal Stenosis with Neurogenic Claudication: A Multi-Site Feasibility Study

Principal Investigator: Charles Penza, DC, PhD VA Facility: Orlando VAHCS

Principal Investigator for Multisite Study: Paul Dougherty, DC, DABCO

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by National Institutes of Health. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you decide to take part in this study, your signature on this consent form will show that you received all the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to compare three different ways to treat lumbar spinal stenosis (LSS) which is a condition that can cause pain and difficulty walking. This study is to prepare for a much larger study to test the effectiveness of manual therapy, exercise, and intramuscular electroacupuncture in reducing pain and improving walking for people with LSS.

You are being asked to participate in this research study because you have had an MRI, CT scan or myelogram that shows LSS, you are 50 years of age or older, and you are having difficulty walking as much as you may like. Your participation in this research will last about 9 months and you will visit the **Orlando VA Healthcare System** about once a week for 3 months, then once a month for an additional 6 months.

This research is being done at three different sites, one in Pennsylvania (University of Pittsburgh), one in Florida (Orlando VA Medical Center) and one in Massachusetts (Boston Medical Center).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to participate in this study because there could be improvement of your pain, because you want to try different kinds of treatment, or because you want to contribute to our general knowledge about treating LSS, which could help others in the future. For a complete description of benefits, refer to the Detailed Information section of this consent.

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WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer for this research study because you are not able to commit to the 9 months of participation, are not interested in being a part of this research study in which you will be randomized (like the roll of a dice) into a treatment, are not interested in receiving these

treatments through a research study or would like to receive treatment outside of the research study for your pain. You may also want to consider other treatments for your LSS that would include: medical management, epidural steroid injections or lumbar decompression surgery.

For a complete description of risks, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

No, participation is not required. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. Other LSS studies may be available. Talk to your provider about such options. Other treatments may be available for LSS outside of research. You can discuss these, as well, with your provider. We do ask that you do not start any new pain medication or get any other treatments for your LSS (e.g., epidural corticosteroid injection, physical therapy, chiropractic, massage, acupuncture) during your participation in the study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is **Charles Penza, DC, PhD** at the **Orlando VA Healthcare System.** If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is **407-646-5075.**

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn whether we can carry out a larger trial to test the effectiveness of combining manual therapy and exercise (MTE), with and without boosters (or follow up sessions) and the combination of MTE and intramuscular electroacupuncture with booster sessions. This study will look at things like our ability to enroll participants, deliver the treatment interventions and collect information about your response to the treatments. All of this information will help us design the larger trial.

HOW LONG WILL I BE IN THE STUDY AND HOW MANY PEOPLE WILL TAKE PART?

This research study is expected to take approximately 3 years. Your individual participation in the project will take 9 months.

About 60 people will take part in this study. About 30 Veterans will take part at the **Orlando VA Healthcare System** and 30 people will take part at the Boston Medical Center. No participants will be enrolled at the University of Pittsburgh.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to take part in this study, below is a description of what will happen. We do ask that if you participate in this study you will not initiate any new pain medications or new treatments for your spinal stenosis during the study time period (nine months).
If at any point in these study procedures you do not want to continue, please just tell the study personnel and we will discontinue.

SCREENING

A research study team member will give you a short memory test to find out if you are eligible to participate in our study at **Orlando VA Healthcare System.** Eligible participants will move on to baseline testing. During baseline testing, there are still screening measures that will indicate if you are or are not able to participate in this study. If you do not pass the memory test, you will not be eligible to participate in the study.

BASELINE

The Site Principal Investigator will perform a brief history and physical examination here at the medical facility to ensure that you are eligible to participate in our study.

If you are eligible to participate in the study, after the history and physical examination, additional information will be collected; age, gender, ethnicity, race, education, weight, height, smoking status and other measures. You will be asked questions about your pain, function, daily activities, mood, medications, sleep habits, and quality of life. You will be asked to walk a short distance (about 13 feet) and we will time how long this takes. You will

also be asked to bend forward as far as you can to measure your flexibility, and to squeeze an object to measure your grip strength.

After Baseline testing you will return home.

RANDOMIZATION

You will then, randomly, be assigned to one of three groups. Randomization is like the roll of a dice. A research study team member will call to let you know the treatments you will be getting and to schedule your first appointment.

No matter which group you are randomized to, you will be followed for 9 months. Every 4 weeks during the initial 12-week intervention phase, an automated email or text message will be sent from the Data Center of the Coordinating Center to you to collect follow-up data. If you do not respond to these messages, or if you do not use a cell phone or e-mail, a research study team member will contact you by telephone to collect data verbally, or you can complete them in-person at your treatment session. Also, at 3 and 9 months you will be asked to return on site to measure your grip strength, walking speed, and the flexibility of your back.

No matter which group you are assigned to, you will come to the **Orlando VA Healthcare System** about once a week for up to 10 times (over a 12-week timeframe). Your appointments will last approximately 30 to 60 minutes, depending on which group you are in. If you are randomized to either of the two groups that have booster treatments, you will be asked to come for additional treatment sessions that are identical to those that you participated in during the first 12-weeks of your study participation, which are about once a month for an additional 6 months. If you are assigned to

the group that does not receive booster sessions, you will be asked to continue simple home exercises, described below, but you will not be required to come to the clinic for additional treatment sessions.

All participants in all 3 groups will be asked to do some simple exercises at home like stretching and some light aerobic activity like climbing stairs or riding an exercise bike. At the end of each treatment session, the provider will show you new exercises to add to your home practice.

You will be asked to do these exercises 1-2 times a day for the length of the study. You will be asked to record the number of minutes that you perform each exercise on a form that we will give you and the number of times you do each exercise. You will bring this form to each visit. You also will be asked to keep track of how often you do the aerobic activity (e.g., climbing stairs, riding an exercise bike).

Participant Name: _____ IRBNet ID: **1784627**

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Summary Table:

Group	Manual Therapy and exercise (MTE)	Manual Therapy and exercise with boosters (MTEB)	Manual Therapy and exercise and Electroacupuncture with boosters (MTEEAB)
Weeks 1-12	Attend weekly sessions (up to 10 sessions)	Attend weekly sessions (up to 10 sessions)	Attend weekly sessions (up to 10 sessions)
Weeks 4, 8, and 12	Answer questionnaires. Undergo brief testing procedures at Week 12.	Answer questionnaires. Undergo brief testing procedures at Week 12.	Answer questionnaires. Undergo brief testing procedures.
Months 4 - 9	- Home exercise, with recording of exercise done - Answer questionnaires at week 24 (by telephone or computer) - Week 36: Answer questionnaires and undergo brief testing procedures on site.	- Home exercise, with recording of exercise done - Monthly treatment visits - Answer questionnaires and undergo brief testing procedures at week 24 and 36.	- Home exercise, with recording of exercise done - Monthly treatment visits. - Answer questionnaires and undergo brief testing procedures at week 24 and 36.
Group	Manual Therapy and exercise (MTE)	Manual Therapy and exercise with boosters (MTEB)	Manual Therapy and exercise and Electroacupuncture with boosters (MTEEAB)
Weeks 1-12	Attend weekly sessions (up to 10 sessions)	Attend weekly sessions (up to 10 sessions)	Attend weekly sessions (up to 10 sessions)
Weeks 12, 24 and 36	Assessments	Assessments	Assessments
Weeks 13 - 36	Home exercise	Home exercise and Monthly visits	Home exercise and Monthly visits.

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PI/SC Approval Date: 1/9/25

LSI Approval Date: N/A

LSI Verification Date: 1/14/25

The Manual Therapy and Exercise group:

If you are part of this group, you will be asked to lie face down on a special table and the treating doctor will deliver gentle movements to your back, hips, and nerves in the legs, as well as massage-type treatment to your lower back. He also will instruct you in stretching exercises that you can do at home. Each session will last approximately 30 minutes.

The Manual Therapy and Exercise with Boosters

If you are part of this group, you will receive MTE as described above, up to 10 sessions over 12 weeks. After these 10 sessions, you will be asked to: come back for one session a month for an additional 6 months.

The Manual Therapy, Exercise and Electroacupuncture with Boosters

If you are part of this group, you will be asked to participate in all the manual therapy sessions including booster sessions described above. In addition, you will receive an electroacupuncture treatment on the same day that you come in for the manual therapy.
Electroacupuncture involves inserting approximately 16 very fine needles in the muscles of your back. Mild electrical stimulation will be applied to the needles that will feel like tapping.

Fidelity Check:

In order to understand the treatments better and to assure compliance with study procedures, you may be asked to allow the provider to share your visit with one of the principal investigators of this study. If you are chosen, the provider will turn on their webcam on the computer and the PI will watch your provider perform the treatment procedures. These visits may be recorded, however the recording will NOT be disclosed outside the VA.

If you are not comfortable with this, you can refuse, and it will not affect your participation in the rest of the study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you take part in this study, it is expected that you:

- Keep your study appointments. If you need to miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Fill out your exercise form as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- While participating in this research study, we ask that you not take part in any other research project without approval from the investigators. This is because participating in one research study could influence the results of another study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

1. Because there may be other risks associated with participating in multiple research studies, tell research staff about any other studies in which you

are currently participating.

2. There is a rare risk that you could fall when asked to do the gait speed test or while doing the spinal flexibility test. This risk will be minimized by having the research coordinator (RC) closely monitor you during these tests.
3. While participating in the exercise program at home, you may experience temporary increase in pain and/or muscle soreness. To minimize this risk, you will be instructed to do as much exercise as you feel comfortable.
4. While undergoing the manual therapy there is a chance that you could experience soreness in the region of the treatment. This soreness typically goes away within 24-48 hours, but if it lasts longer, let the doctor who administered the treatment know so they can adjust the sessions in the future. There is also a rare chance that you could experience more serious side effects including fracture or disc injury. These effects are very rare.
5. As may occur during routine clinical practice, you could experience temporary increase in pain during or following the physical examination, or the electroacupuncture procedure. We estimate that this occurs less than 10% of the time and it is not a serious risk.
6. Risks associated with acupuncture include bleeding, infection, sleepiness, and lightheadedness. All these risks are rare. Bleeding and infection occur less than 0.1% of the time, and somnolence/lightheadedness occur less than 5% of the time. Temporary increase in pain lasting a short period of time (less than 24 hours) after an acupuncture session may occur and is rare, occurring less than 5% of the time.
7. You may feel uncomfortable while answering some questions, and in our experience, this occurs in less than 1% of participants. You can skip any questions you do not want to answer.
8. As private information is collected as part of the study, there is a risk to privacy and confidentiality. Every effort will be made to ensure your privacy and confidentiality are maintained.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. If you become pregnant, there is an unknow risk to the fetus.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We cannot promise that you will benefit from taking part in this research study. Possible benefits may include reduction of pain and improvement in the distance that you can walk before you experience pain. Even if you do not achieve direct benefit from taking part in this research study, you will contribute to the acquisition of knowledge that could help others.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Instead of joining this research study, you may work with your medical providers both within and outside the VA to find effective treatments for the symptoms you are experiencing because of lumbar spinal stenosis (LSS), or you may elect not to pursue additional treatment at this time. Many of the treatments under study in this project are already available to Veterans within the **Orlando VA Healthcare System.**

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. Some information will be collected directly into a protected electronic system on a secure drive, to which only research team members will have access. Some information will be collected on paper, which will be kept in secure, locked buildings to which only research team members have access.

You will be assigned a unique code number. This number will be used to reference your participation in the study and only local research staff members at your site will have access to this number. We will include information about your study participation in your medical record.

Your information will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study: The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the Food and Drug Administration (FDA), the VA Office of Research Oversight, Data Center at the University of Pittsburgh, Institutional Review Boards at the VA, our local Research and Development Committee, and other study monitors.

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.

The University of Pittsburgh is the Coordinating Center and will have access to data, which may include identifiable data for the purposes of conducting this study. The University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. The Coordinating Center may contact you to complete assessments of your progress. The NIH may have access to identifiable data as well as the study sponsor.

At some point, your identifiers might be removed from the private information. This de-identified information may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

We will store your data in conjunction with VA regulations. Information will be shared with other researchers in the future, but those researchers will not be able to identify you. Your de-identified data may be used in any type of research. Your de-identified data may be shared with others, including federal repositories, and will be shared without identifiers.

If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to inform, as required by state law, the appropriate agencies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use

information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

We will include information about your study participation in your medical record.

When the study is completed (including all data analysis) then the identifiable information will be destroyed per the policy of the Veterans Health Administration (Directive 6300 – Record Control Schedule 10-1)

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as diagnoses, progress notes, medications, lab or radiology findings.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office, The University of Pittsburgh Office of Research Protections, National Center for Complementary and Integrative Health (NCCIH) at the National Institute of Health (NIH), an independent monitoring committee, the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program (HRPP).

For payment processing, your information may be shared with the **South Florida Veterans Affairs Foundation for Research and Education (SFVAFRE)** which is a non-profit corporation to support research service at the **Orlando VA Healthcare System.**

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, **Charles Penza, DC, PhD** and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will be paid up to $150 for your full participation in this study. Specifically, we will provide $25 compensation following the completion of baseline data collection, $50 following completion of the 3-month data collection, and $75 following completion of the 9-month data collection. You may choose to receive your payment via Greenphire ClinCard or check.

*If you choose to receive payment via **ClinCard:***
In order to provide you with your reimbursement, you have the option of receiving a Greenphire ClinCard. The Greenphire ClinCard is a MasterCard Debit Card and can be used anywhere MasterCard is accepted. In order to receive your compensation via the ClinCard, we will need to send Greenphire your name; your date of birth, address and social security numbers will NOT be used. If you do not wish to share this information with Greenphire, you will receive your compensation via a check in the mail, which you will receive within 4-6 weeks of each completed study visit.

This debit card will be activated by the study team upon your first clinic visit. Immediately following each qualifying clinic visit, the study team will load the ClinCard with the allotment payment amount. When visits are completed, funds will be loaded onto your card. You will be able to use the

funds in approximately 2 business days. Please talk to the study team if you have any additional questions regarding the reimbursement ClinCard.

*If you choose to receive payment via **check**:*
You consent to the release of personally identifying information about you including your name, address, and social security number to the **South Florida Veterans Affairs Foundation for Research and Education (SFVAFRE)** so that we may provide compensation to you. You can expect to receive a check within 4-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government" to include the non-profit corporation if they will issue the funds and need the subjects' information to do so.

If payment is made to you by the VA (whether by check, direct deposit, or a VA issued debit card), an IRS Form 1099 will be generated regardless of the amount you are paid. If you do not receive payment within 6 weeks, you may contact the study team at the **Orlando VA Healthcare System at 407-631-9673.**

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance with study procedures.

Financial compensation is not available for such things as lost wages, disability, or discomfort due to an injury. The Department of Veterans Affairs

does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.

If you should have a medical concern or get hurt or sick because of taking part in this study, call: ***Kayla Patterson, MSN, RN at 407-631-9673 or 407-405-7165.*** *In case of emergency, call* ***407-631-4100.***

DURING THE DAY:

Dr. **Charles Penza, DC, PhD** at **407-646-5075** and

AFTER HOURS:

Dr. **Charles Penza, DC, PhD** at **407-590-6443**

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights, and you do not release the VA from any liability by signing this form.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. If you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or decide to leave the study early, you will not lose any benefits to

which you are entitled. If you wish to suspend active participation and restart at a later date, please contact the study team. If you do not take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw from therapy, you will be asked to complete remaining evaluations, but again, this is voluntary, and you will not be penalized for declining. If you withdraw from the study, data that has already been collected as part of the study can be utilized by the study team, but no future data will be collected without your permission.

If you wish to stop active participation in the study, the site study staff may ask you if you will agree to allow us to continue to collect medication use and healthcare service use data via VA databases for the time of the study (9 months post baseline). If you agree to future data collection, then you will be placed on a reduced participation status. If you do not agree to medication and healthcare use data collection via VA databases, then you will be withdrawn from the study.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Once you sign the Informed Consent and HIPAA Document, you will be officially enrolled in this study. The first test you will be given is a memory test. If you do not pass, you will be withdrawn from the study, and we will notify your primary care provider. No additional data will be collected. You will still be paid $25 for your time.

The research team may stop your participation in the study if they believe it is in your best interest or if you are not following study requirements for treatment or evaluations. If so, the study staff will explain the reasons and arrange for your usual medical care to continue. Termination from the study will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions regarding this study, if you experience side effects or want to report a research-related injury or illness, or if you have any additional concerns or complaints while you are participating in this study, you can contact the site investigator Dr. **Charles Penza, DC, PhD** at **407-646-5075.**

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 or email vacentralirb@va.gov if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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PI/SC Approval Date: 1/9/25

LSI Approval Date: N/A

LSI Verification Date: 1/14/25

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available about the therapies being studied that might change a person's decision to stay in the study. If this happens, the study staff will tell you about it and discuss with you whether you want to continue in the study.

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. **Charles Penza, DC, PhD** or designee has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent. A record of signing this consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
_____	_____	_____
Participant's Name	Participant's Signature	Date

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