Effects of novel SCS paddle on intraoperative neuromonitoring recording

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A. STUDY BACKGROUND AND PURPOSE

Purpose:

The purpose of this study is to demonstrate safety and efficacy of a new spinal cord stimulation paddle electrode which is able to target the dorsal horns, dorsal nerve roots, and dorsal columns. The research electrode ("Study Electrode") is designed to answer basic physiological clinical research questions. It may inform future device therapy development, but the Study Electrode is not a product that will be marketed or sold. The Investigators believe the protocol is a Non-Significant Risk study answering basic physiological research questions, which may be performed under hospital IRB approval.

Background:

Spinal cord stimulation (SCS) has successfully treated chronic extremity pain for many years, providing an alternative to dependency on chronic opioids.[1] Multi-center trials have reported that 60% of patients have more than a 50% reduction of intractable extremity pain from Failed Back Surgery or Complex Regional Pain Syndrome (CRPS) at 6 months.[2-5] Outcomes over the last several years have appeared more promising (advanced algorithmic programming, 10 kHz, BurstDR).[6-18] Theoretical commonalities of these techniques include stimulation of targets other than the dorsal column. Mounting evidence suggests that pain relief may be more pronounced with modulation of the dorsal horn, through activation of inhibitory interneurons.[19] Therapies which mechanistically target the dorsal horn have been noted to provide superior benefit for treatment of axial low back pain, an affliction far more common than isolated extremity pain. In addition, an additional form of stimulation (dorsal root ganglion stimulation (DRG stimulation) has gained traction for treatment of CRPS and has provided benefit to patients who previously were difficult to treat with traditional SCS (i.e. patients with isolated foot, knee or groin pain). Thus, targeting the dorsal horn and DRG has the potential to dramatically increase the number of patients that may benefit from SCS.

Conventional SCS electrodes however are limited in delivery of therapy to the dorsal horn and the DRG. Specifically, current paddles limit selective targeting of this region because they are too stiff, thick, and bulky volume to be positioned adjacent to nerve roots without nerve root compression. Additionally, the spacing and location of electrode contacts has not been optimized for this target. Thus, without addressing the critical unmet need, the revision rates with targeting these new targets will remain like traditional SCS (15-20%) and efficacy is likely to wean over time in a large percentage of patients who then discontinue therapy.

To overcome these limitations, our industry partner is developing a high-resolution, 64-electrode SCS fully-implantable therapy based upon work funded by the NIH, NSF, and DARPA. The fully-implantable therapy is based upon a high-resolution paddle electrode which has 8-columns of low-volume, ultra-thin electrode contacts which span laterally between the left and right lateral dorsal roots. Low-volume and conformal coupling to the dura with ultra-thin lead technology may enable direct stimulation of dorsal horn and dorsal root entry zone (intraspinal connection to the DRG) in addition to dorsal columns using a single electrode array. We are currently in the process of preparing an NIH UH3 proposal to perform clinical translation of the next-generation HD64 therapy system and to demonstrate clinical efficacy, safety, and feasibility. However, the scope of this IRB protocol is to demonstrate basic physiological clinical research feasibility of only the paddle electrode array in a non-implanted, intraoperative surgical context. The paddle electrode will be tested intraoperatively using a clinically safe external stimulator.

For the basic physiological research study, we will recruit 10 subjects and perform a non-implanted, temporary, intraoperative assessment of the paddle electrode to determine if the electrode contact arrangement can selectively target columns and dorsal roots as verified by neuromonitoring in patients who are undergoing a standard-of-care spinal cord stimulation procedure. [20, 21] Figure 2 shows a comparison between the standard-of-care lead we currently use in over 50% of paddle implants and the Study Electrode. The Study Electrode is a research electrode that will be designed and manufactured specifically to enable the intraoperative basic physiological pilot study but will not be

marketed or sold. The pilot study results may be used to inform the design of the future therapy device. The PI and Industry Sponsor are currently also writing an NIH translational development grant to further optimize the high-resolution therapy electrode and testing of the fully-implanted system.

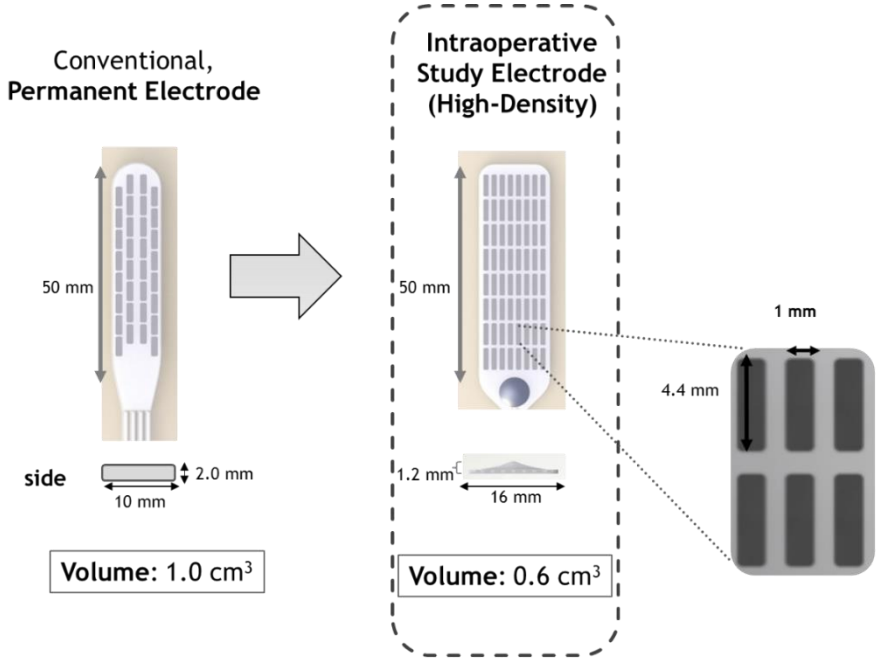

Figure 2. A conventional, Permanent Electrode is shown on the left (Boston Scientific CoverEdge32) which provides 4 columns of stimulation contacts. The low-volume Study Electrode provides 8 columns of stimulation contacts for greater selectivity (8 x 8 high-resolution configuration).

B. STUDY DESIGN

1. Twenty patients offered SCS for standard of care will be invited to participate in this study. With the study electrode in place, we will be using intraoperative neuromonitoring per our routine standard-of-care. Demographic information will be collected including patient age (years), gender (male/female), duration of illness and medications with doses and frequency. Stimulator settings used for testing will be documented. Additional data about pain, disability and psychological status will be

collected prospectively at baseline. Peri-operative imaging will include standard of care pre-operative MRI/CT, intraoperative fluoroscopy, and post-operative scans. Anesthesia type and routine somatosensory evoked potentials (SSEP) and motor evoked potentials (MEP) will be documented. Once intraoperative neuromonitoring is complete, the permanent electrode will be placed and programming will occur using the permanent electrode. Patients will fill out the following questionnaires to gauge pain level pre-operatively and postoperatively as per Prospective Observational Study of Outcomes following Neuromodulation for Pain InfoEd Study #3484: Numerical Rating Scale (NRS), McGill Pain Questionnaire (MPQ), Oswestry Disability Index (ODI), Pain Catastrophizing Scale (PCS), Beck Depression Inventory (BDI) and pain medication usage. Patients will return for a follow up programming session (with the implanted device) on post op day 1, and 3 months post-op as per standard of care. At these times patients will be asked to complete the outcome surveys listed above. The BDI tests for depression. If the research staff believes the patient may harm themselves based on their answers, the PI/treating physician will be notified, and help will be offered to them.

2. The proposed clinical study is summarized in Figure 3 with the left column describing the clinical standard of care procedure the patient will undergo and the right column indicating the additional Non-Significant Risk steps which the enrolled subjects would also undergo (additions shown in blue).

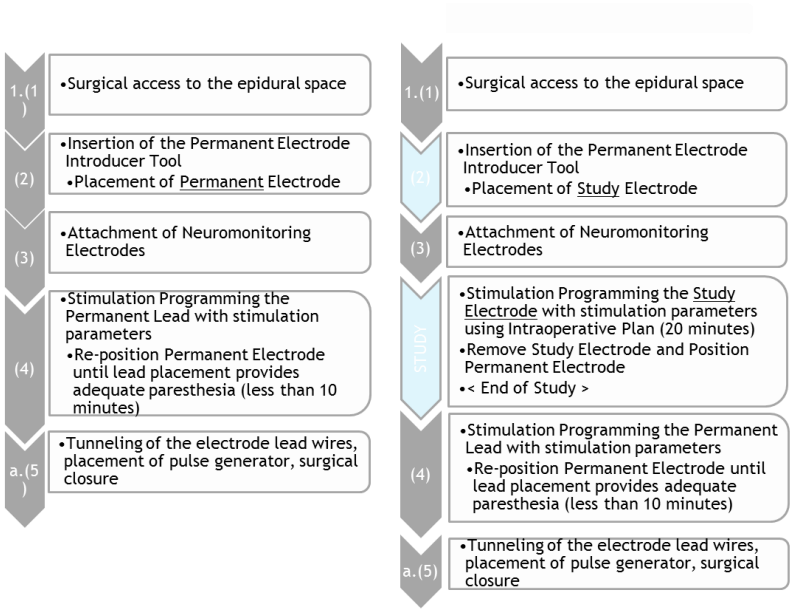

Figure 3. The standard of care procedure flow (left) is compared with the proposed study protocol (right).

Study Electrode (Micro-Leads, Inc., Boston, MA)

The high-resolution Study Electrode (Figure 2, middle) will be used to answer clinical research and scientific questions associated with performing high-resolution spinal cord stimulation. The Study Electrode will feature an array of 8 columns of stimulation contacts arranged in 8 rows with a low-volume electrode body. This array of stimulation electrodes contact patterns of bi-poles and tri-poles (Supplemental Materials, Appendix C) may be applied to the spinal cord for assessment of dermatomal selective stimulation patterns.

The Study Electrode will be manufactured specifically for this pilot study and will not be marketed or sold as a commercial product. The Study Electrode will be manufactured, tested for biocompatibility, sterilized with Ethylene Oxide, and provided in a sterile, double-pouch packaging with safety labelling according to 21 CFR 812.5. The Study Electrode will have multiple lead tails, at least three feet in length with non-implantable proximal connectors. The Study Electrode connectors will be physically

large (2 cm x 4 cm) to facilitate ease of intraoperative handling and to uniquely constrain the use of the lead to the intraoperative session.

Study Pulse Generator System

The focus of this study is to evaluate clinical feasibility of only the Study Electrode (but not the fully-implanted system), and to connect the Study Electrode to a clinically safe external pulse generator through a switch matrix.[22] The pulse width and frequency will be varied per standard of care. Pulse amplitude will be varied in 0.2 mA steps from 0 to 10 mA which are the same parameters used for clinical standard-of-care.

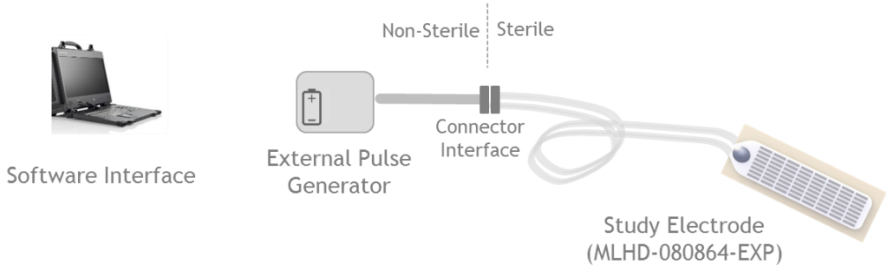

Figure 4. The Study Electrode will be connected to an external pulse generator using a sterile cable. The stimulation amplitudes will be changed along with different electrode contacts.

Detailed Intraoperative Description

Step 1. Surgical access to the epidural space (Standard Procedure, +0 minutes)

A standard-of-care spine exposure will be performed. The incisional location is planned through evaluation of preoperative x-rays with metallic markers overlying the spine. An initial incision is made through the skin, midline over the posterior spinous process. Through use of electrocautery and surgical dissection an approach is created to the spine. Intraoperative x-rays are taken to confirm the operative level of the spine. Using complex spine surgical instrumentation, a partial hemilaminectomy is performed. Subsequently, the ligamentum flavum is dissected at this location to expose and access the epidural space.

Step 2. Insertion of the Introducer Tool and Permanent Lead (Modified Procedure)

Step 2-a (Standard Procedure, +0 minutes). The surgical site will be prepared for the Permanent Electrode pocket size and shape as the standard of clinical care. A dummy electrode introducer tool or paddle electrode is introduced into the posterior epidural space using bayonet surgical forceps. The positioning of the Permanent Electrode typically requires multiple positioning iterations (Repeat of Step 2), as well as additional surgical dissection and bone/tissue resection, prior to adequate lead placement position.

If there are any noteworthy surgical issues deemed by the surgeon to pose procedural risk or complication, the Study will not be performed on the patient, and the surgical procedure would continue according to clinical standard of care.

< Commencement of Study (20-minutes) >

Step 2-b (Investigational Procedure, + 3 minutes). After the surgical site has been prepared per standard of care for the Permanent Electrode, the Study Electrode will be taken from the sterile packaging and positioned within the surgical site. The placement of the Study Electrode will be considered commencement of the study.

Step 3. Neuromonitoring Session will Commence. (Standard Procedure, +0 minutes)

Once the surgeon is reasonably confident in the location of the electrode, the neuromonitoring session will begin. The Study Electrode position may be verified by x-ray.

Step 4. Stimulation programming: (Investigational Procedure, + 20 minutes)

Once the neuromonitoring is confirmed to be operational, the Study Electrode will be stimulated using multiple contact Groups.

Step 4-a. Stimulation with Study Electrode (Investigational)

The stimulation patterns and pulse patterns will be selected by the neurosurgeon to deliver stimulation therapy to the chosen electrode contact configurations (refer to Supplemental Materials Appendix C on stimulation contact configurations) estimated to provide selective dorsal column activation. Approximately 10-20 electrode contact Groups will be performed during the study. Paresthesia maps will be created according to the region in which the neuromonitoring reports EMG activation.

Initially a central electrode bi-pole or tri-pole will be used, and the stimulus amplitude will be increased until neuromonitoring is used to identify an activation threshold (frequency will be fixed). At that time, 10-20 predefined stimulation electrode Groups will be stimulated (see Supplemental Material Appendix C for exemplar electrode patterns) at an amplitude below threshold. The various electrode Groups will be created using the Study Electrode in low-resolution and high-resolution configurations. Low-density electrode configurations will use 2 or more electrodes as a grouped-contact while high-resolution will use only one electrode. After the first group of stimulation contacts is activated, the EMG patterns will be recorded. Group 1 of stimulation contacts will be de-activated. A Group 2 of stimulation contacts will be activated, followed by recording the EMG responses. It may be necessary to alternate and re-activate Group 1 to verify repeatability. Group 3-Group 20 will be sequentially performed. This study procedure will be allowed for approximately 20 minutes, which should be

sufficient to collect the necessary data of high-resolution electrode contact patterns. A designated team member will record the EMG results (see case report form, Appendix A). Once the study data is collected, the Study Electrode will be removed from the subject.

< End of Study >

Step 4-b. Stimulation with Standard Electrode (Standard Procedure)

The procedure will continue as standard of practice. The Permanent Electrode will be placed and tested (Step 4) using the standard of care lateralization using Neuromonitoring. Once the location is confirmed, the Permanent Electrode may then be secured using sterile Nurolon suture per standard of care.

Step 5. Tunneling, Implant of the battery, and surgical closure (Standard Procedure)

The Permanent Electrode tails (wires) are tunneled beneath the skin to the location of the battery implant. The tails are connected to the header of the battery, and the device itself is tested for good conduction of the lead contacts. Once this is confirmed, small torque screws are tightened using a dedicated screwdriver. The IPG is placed and secured within the tissue pocket.

All surgical incisions are closed using a multi-layered suture technique for optimum wound healing. Dermabond is utilized on the incision after closure to provide a further integrity to the skin and create an antimicrobial barrier during epithelialization.

C. SUBJECT POPULATION (WHO, WHAT, WHERE)

i. The subjects will be AMC neurosurgery patients with chronic pain who are undergoing or have undergone a neuromodulatory procedure (SCS).

ii. Subject population will include 20 adults ≥ 18 years old.

iii. Patients participating in this study must also be fluent in English as well as mentally competent to read and answer the questionnaires, as well as complete pain assessments exams.

iv. All patients must be able to give informed consent.

D. DATA ANALYSIS

i. De-identified data will be provided to Dr. McLaughlin at Micro-Leads, Inc. for the following analyses.

ii. Statistically valid results are not the intent of investigational pilot studies, though the studies should still be performed with a purpose, enroll appropriate subjects, use meaningful endpoints, and capture relevant information to inform further device development.

iii. The proposed study will identify a paresthesia stimulation threshold, and then perform mapping between the dermatome where EMG-based Neuromonitoring demonstrates activation. Multiple Study Electrode contact Groups will be stimulated and recorded as to where the EMG recruitment is generated. The Groups will be designed to demonstrate selective stimulation, low-back stimulation, and bilateral paresthesia coverage. According to standard procedure, the Permanent Electrode is activated using multiple stimulation groups. Stimulation groups for the Study Electrode will be chosen such that at least two electrode Groups will be identical to those used for the Permanent Electrode. Additionally, the Study Electrode will be configured using low-density and high-resolution patterns as a direct comparison. The selectivity of paresthesia will be characterized for these Study Electrode configurations. The data will be analyzed to determine trends across subjects in whether the high-resolution stimulation improves the targeting of therapy to a focal number of dermatomes.

iv. The study hypothesis is that the high-resolution Study Electrode will generate paresthesia that is focused to a more selective (smaller) dermatomal region than the currently available paddle electrodes according to the paresthesia maps. We further hypothesize that the Study Electrode will provide dorsal root activation and bi-lateral activation. We finally hypothesize that the Study Electrode may selectively provide paresthesia to the lower-back dermatomes. We do not believe that the Permanent Electrode will be able to achieve these outcomes.

v. The study is designed to perform a relative comparison between high-resolution and low-density Electrode Groups using the Study Electrode. Repetitive stimulation contact Groups may be used (as defined in the protocol) to ensure repeatability of EMG responses. Statistical analysis of Study Electrode contact Groups will be explored but may are not expected to be statically significant as the exact surgical position of the electrodes will be different for each subject. The analyses will be compared between the stimulation amplitudes between the high and low-density Groups.

vi. We will compute a dermatomal heat-map describing the stimulation dermatome observed by EMG. The 10-20 Groups of stimulation will allow us to answer the specific research questions:

vii. (1) Can specific dermatomes be selectively activated (e.g. low-back, foot) using the high-resolution Study Lead? Which off-target dermatomes are activated?

viii. (2) Can dermatomal selectivity be observed between low-resolution and high-resolution contact configuration?

ix. (3) Does the reduced volume improve the surgical positioning of the lead in the epidural space?

x. Data will be captured only during the intraoperative session. No other data will be collected.

E. RISKS

Non-Significant Risk Categorization of the Proposed Study

The Study Electrode is a research electrode designed to answer basic physiological clinical research questions. It may inform future device therapy development, but the Study Electrode is not a product that will be marketed or sold. Studies which are Non-Significant Risk (do not meet the Significant Risk Criteria) do not require applications for IDE to the FDA and are considered approved under the Abbreviated Requirements of the Investigational Device Exemption regulation 21 CFR 812.2 (b). Abbreviated Requirements stipulate that Non-Significant Risk studies have hospital IRB approval, informed consent, and appropriate subject monitoring, package labelling, etc. The section below describes the rationale for why the protocol is believed to be a Non-Significant Risk, basic physiological research study according to the guidelines. The protocol using the Study Electrode is not believed to have a higher risk profile than the clinical standard of care procedure.

Rationale for Non-Significant Risk

The Study Electrode is a research electrode specifically designed to answer basic physiological clinical research questions for this study. Non-Significant Risk Studies do not require IDE applications, and considered approved when performed under hospital IRB, informed consent, subject monitoring, reporting, and labelling. The Investigator believes the protocol and investigational device Study Electrode do not meet the Significant Risk criteria (listed below from 21 CFR 812.3 (m)). A rationale is provided below as to why the Investigator believe the Study Electrode and protocol do not satisfy the Significant Risk criteria. Accordingly, the study is Non-Significant Risk, does not require an application for IDE, and is considered already approved for investigation under hospital IRB oversight, informed consent, labelling, and subject monitoring.

1. **Criteria 1:** The device is not intended as an implant;
    a. **Rationale:** The Study Electrode is not intended for use as a permanent implant.
    b. **Rationale:** The Study Electrode is intended for a brief intraoperative test session.
2. **Criteria 2:** It is not purported or represented to be for a use in supporting or sustaining human

life;

a. **Rationale**: The Study Electrode or proposed protocol is in no way used to support or sustain human life.

3. **Criteria 3:** It does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject;
    a. **Rationale**: The Study Electrode will be positioned into a pre-existing pocket created by the standard of care procedure and FDA-approved paddle dummy electrode tool.
    b. **Rationale**: During the standard-of-care implantation procedure, a spacer dummy electrode from the clinical kit is inserted into the epidural space. After removing the dummy electrode, the Permanent Electrode is inserted positioned and aligned anatomically and physiologically to maximize the therapy benefit to the patient. In this study, the temporary placement of the Study Electrode will mimic the placement of the dummy electrode, having the same risk profile. The Standard of Care intraoperative trialing session lasts approximately 10 minutes to verify electrode placement. The proposed Protocol extends this trialing session by up to 20 minutes. As the subject will be asleep, the additional time is believed to be a Non-Significant Risk to the patient.
4. **Criteria 4:** It is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease at this early stage.
    a. **Rationale**: The Study Electrode is not intended to perform any diagnosis, cure, mitigation, or treatment of disease.

Based upon the criteria for, the Study Electrode does not qualify as a Significant Risk device. Non-Significant Risk device investigations are considered already approved for IDE under the Abbreviated requirements of hospital IRB, informed consent, and package labelling.

Outcomes of Prior IRB-Approved Neural-Stimulation and Recording Studies Performed in the United States

Neural stimulation and recording studies with investigational study devices have been successfully performed around the country under IRB approval as is proposed by this protocol. As summarized in Table 1, NSR studies range from intraoperative stimulation and recording in the brain to spinal recording, to placement of intraoperative epilepsy electrodes, to 30-day percutaneous implantation of electrodes on peripheral nerves of amputees. [23-28] The proposed non-implanted, 20-minute, Study Protocol is believed by the Investigator to have a Non-Significant Risk profile, particularly in the context of other NSR studies that have been successfully performed.

Table 1. IRB Approved Intraoperative and Short-term Implanted Studies of Neural Recording and Stimulation Protocols

Purpose & Outcome	**Reference**
Deep Brain Stimulation	
Investigation of deep brain stimulation mechanisms during implantable pulse generator replacement surgery	[23]
Measurement of evoked potentials during thalamic deep brain stimulation	[24]
Studying task-related activity of individual neurons in the human brain	[25]
Intra-operative behavioral tasks in awake humans undergoing deep brain stimulation surgery	[26]
Neurophysiological Monitoring during Spinal Cord Resection Surgery	
Warning criteria for intraoperative neurophysiologic monitoring	[27]
Peripheral Nerve Stimulation (30 day implanted)	

Restoring motor control and sensory feedback in people with upper extremity amputations using arrays of 96 microelectrodes implanted in the median and ulnar nerves.	[28]

There is a possible risk that the contacts could break due to the size and fragility of the device. However, proper safety and friction testing including: a surgical simulation test, simulated tissue spine model test, and destructive mechanical insertion tests (frictional handling and insertion into a low-volume, narrow cavity) have been conducted by the manufacturer to ensure that this is a minimal risk. This will be explained to the patient. Minor risks of the proposed study include loss of confidentiality and increase in OR time by 20 minutes, which is within the normal variation of OR cases. Patients' names will only be associated with the data that is collected on a master list that will be kept on a password protected computer. A small risk of loss of confidentiality is present. Patients will be returned to the stimulation parameters most efficacious at controlling pain at the end of testing. Though thresholds are monitored carefully, there is a risk of discomfort.

F. BENEFITS

While we cannot promise any benefits to the patients in this study, there is the possibility of personal benefits to the participants of the study if a better lead becomes available in the future. Additionally, data obtained from this study may improve our knowledge of the effects of stimulation to aid future SCS patients in improved device programming.

G. CONFIDENTIALITY

PHI will include patients' name and date of birth. All data including the subject's name, electrophysiological data, video recordings obtained in clinic, and demographics will be kept on a password protected computer in a locked office in the AMC hospital. Each subject will be given a unique number and the collected data will be stored under that number. The master list linking patients' to their coded data will be password protected and only key study personnel will have access

to the master list. The master list of data will be stored indefinitely following the completion of the study.

H. OPTIONS

Patients have the right to opt out of the research study with no change in their normal standard of care.

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ALBANY MEDICAL CENTER
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CONSENT TO TAKE PART IN A HUMAN RESEARCH STUDY

AND

HIPAA Authorization (Health Information Privacy Rights)

Title of research study: Effects of novel SCS paddle on intraoperative neuromonitoring recording (5151)

Principal Investigator: Julie G. Pilitsis, MD, PhD

Site: Albany Medical College, 47 New Scotland Avenue, Albany, NY 12208

Study-related phone number: (518) 262-5088

You are being asked to take part in a research study because you have chronic pain and will undergo a spinal cord stimulation surgery.

What you should know about a research study

- Please read this consent form carefully. The consent will explain the purpose, risks, and possible benefits of taking part in this research study.
- The main goal of regular medical care is to help each patient. The main goal of a research study is to learn things to help future patients.
- We cannot promise that this research study will help you.
- Just like regular medical care, your taking part in this research study can result in harmful effects that may be minor or serious.
- Someone will explain this research study to you. Make sure all your questions are answered before you make a decision.
- Being in a research study is voluntary. Whether or not you take part in this research study is up to you. Also, if you agree to take part now, you can change your mind later on.
- Whatever you decide, it will not affect your access to health care, treatment, and services not related to the research.

1 - Why is this research study being done and what is its purpose?

We want to measure whether a new spinal cord stimulator paddle can more effectively stimulate the region of the body where you and others have pain. The device we are studying is investigational, but physically very similar to currently FDA-approved spinal cord stimulator leads that are permanently implanted in

people. We will only be testing this paddle during your surgery. This means we will be confirming proper placement of the paddle over the spinal cord, using a battery to send an electrical pulse to the paddle and measuring the ability of the paddle to stimulate targeted areas of your spinal cord. It will not be put in place permanently.

2 - Who is doing the research study?

Julie G. Pilitsis, MD, PhD is in charge of this research study. We expect about 20 people at Albany Medical College will be in this research study.

3 - What can you expect if you take part in this research study?

If you choose to participate in the study, we will extend the time of your surgery by about 20 minutes. During that time, we will test the new spinal cord stimulator, to see if we can stimulate additional areas of your body (chest, abdomen, legs, back). After we have tested this temporary device, we will remove it and continue with the planned surgery. After surgery, you will receive the same care as someone who has not participated in this study. The next day you have a follow-up programming session. Three months later as part of return follow-up you will complete surveys to show how you are doing: Numerical Rating Scale (NRS), McGill Pain Questionnaire (MPQ), Oswestry Disability Index (ODI), Pain Catastrophizing Scale (PCS), Beck Depression Inventory (BDI) and pain medication usage. The BDI tests for depression; if the research staff believes you may harm yourself based on your answers, we will offer you help. We will share your deidentified testing data with the company who made the new stimulator and the FDA to show why this paddle may help others in the future.

4 - What are the risks and possible discomforts?

The operative risks of this study are no different than for the underlying spinal cord stimulation implant including a possible risk that the contacts could break. However, proper safety testing including a friction test has been conducted by the manufacturer to ensure that this is a minimal risk. You will be asleep throughout the procedure and should not experience any additional discomfort. The most significant risks for the spinal cord implant procedure you are receiving include spinal cord/nerve injury and paralysis, bleeding, pain, and infection. However, these risks are not increased by the placement of the study electrode. You may also receive an additional x-ray to verify positioning of the electrode. Because we typically use between 3-8 x-ray images during surgery, this is a minor additional risk. At present, there is no evidence that the additional radiation absorbed by your body will cause any health effects.

As in all research studies, there is always a risk of loss of confidentiality. However, all research related images, test results and questionnaire data will be stored separate from your name. Every effort will be made to protect your confidentiality. All research information collected will be kept in a study folder and not placed in your medical record.

5 - What are the possible benefits?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include an improved understanding of the effects of stimulation methods. This could ultimately help offer better pain relief to a greater number of patients.

6 - If you do not want to take part in the research study, are there other choices?

You are free to choose not to take part in this research study.

7 - If you have any questions or problems, whom can you call?

You should call Dr. Pilitsis at (518) 262-5088 if you have any questions, or Michael Gillogly our research coordinator, at (518) 262-2180 for any problems, or if you think you have been injured**.**

If you cannot reach Dr. Pilitsis, and have complaints about this research study, or you have questions about your rights as a research subject, you may call the Albany Medical College Office of Research Affairs at (518) 262-5182.

8 - What information will be kept private?

We cannot guarantee privacy. However, efforts will be made to keep your personal information and other health information, including research study records and medical records, private. You will be identified as a research subject for medical records and billing purposes.

Authorization (Permission) to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

If you have questions about your privacy rights, please call the AMC Privacy Officer at (518) 264-8477.

What information about you may be used and given to others?

Information that identifies or can be used to identify you such as your address, your date of birth, your health information, and other similar personal information may be collected for this study.

Your health information that may be used for this study and given to others can be in different forms and may include:

- Written information, such as what is in your medical chart, or the record of your study visits
    - Electronic information, which is information stored in computer systems, such as billing data
    - EEG and tests performed during your surgery
- Verbal information, such as in phone calls made as part of this research study Information obtained during this research about:
        - Past and Present Medical History
        - Physical exams
        - Laboratory, x-ray, and other test results
        - Study procedures, treatments and follow up

Who will be able to use your health information and give it to others?

Information about your health may be used and given to others by the study doctor and his/her study team. They will see the research information during and after the study.

Who will be able to get your health information and how and why will they use it?

Information about you and your health that might identify you may be given to others to carry out the research study.

Information about you and your health that might identify you may be given to:

- US Food and Drug Administration (FDA) and/or the Department of Health and Human Services (DHHS)
- The Albany Medical Center Institutional Review Board (IRB), which is a group of people responsible for protecting your rights and welfare and is not involved in the conduct of the clinical study.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be made known.

If you give written permission to release your health information, the information may be shared with you and others and no longer be protected by the privacy regulation.

Will you be able to see your research records?

You will not be allowed to see your research records.

When will the research end and when will your health information no longer be used?

This permission will remain in effect until the end of the research study.

What if you don't want to give your permission to be included in the research and don't want anyone to give out and use your health information?

If you do not give us permission by signing the permission (authorization) form, you will not be able to be in this research.

You can give us permission to use and give out the health information listed above for the purposes described above by signing this permission (authorization) form.

Can you stop taking part in the study early?

If you are unable or unwilling to complete the study, you may end the session at any time. If you have questions after leaving the appointment, you may call our research coordinator, Michael Gillogly at (518) 262-2180.

You may decide to not continue in the research study at any time by telling your study doctor. It will not affect your access to health care, treatment, and services not related to the research.

You may cancel your permission for us to use and disclose your health information at any time. You do this by sending written notice stating you wish to cancel your permission. Send this to the study doctor. If you cancel your permission, you will not be able to continue being in this study.

When you cancel your permission, no new health information, which might identify you, will be gathered after that date. Information gathered before you cancel your permission may still be used and given to others. They might use the information to complete analysis and/or reporting for this research.

9 - Can anyone else remove you from the study?

Dr. Pilitsis can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research including any new findings that develop from this research during the course of the research.

10 - What else do you need to know?

If you are injured as a result of taking part in this research study, medical services needed to treat such injury will be made available to you at Albany Medical College. No funds have been set aside for the cost of the medical treatment and it will be billed to you or your insurance company. AMC will not accept financial responsibility for the cost of such services. This paragraph relates only to billing and payment for services provided and does not release AMC from responsibility for its negligence or intentional wrongdoing, if any. By signing this consent form, you have not given up any of your legal rights.

DO NOT SIGN
LATER THAN EXPIRATION DATE OR
IF THERE IS NO EXPIRATION DATE ➡

ALBANY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
APPROVAL EXPIRES:
FEB 16, 2022
ISSUE DATE: 07/02/2021

PERMISSION OF RESEARCH SUBJECT AND HIPAA AUTHORIZATION

Approval of research subject:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
Consent obtained by:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)		**Title**	
Witness:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
A witness is required when the subject cannot read, and the consent document was read to the subject. The sponsor may also require a witness.			
We will give you a signed and dated copy of this Consent Form.			