St. Luke's University Health Network
Informed Consent Document for Human Subjects Research

Department: Neurosurgery

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Medical Study Title: NAPS (Non-awake versus Awake Placement of Spinal cord stimulators) Study for the evaluation of awake and non-awake methods of SCS paddle lead placement

Lay Study Title: A Study to determine whether non-awake placement is comparable to awake placement of spinal cord stimulators for achieving paresthesia coverage in chronic pain patients

Sponsor: St. Luke's University Health Network with Funding from St. Jude Medical

What Is Informed Consent?

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a committee that reviews, approves and monitors research involving humans. Before you can make a decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

You should understand that your relationship with the study doctor is different than your relationship with your treating or personal doctor. The treating doctor treats a specific health problem with the goal of improving a medical condition. A study doctor treats all subjects according to a research plan to learn about the experimental drug, device or procedure being studied and with the understanding that you may or may not benefit from being in the study. You should ask questions of the study doctor and/or study team if you want to know more about this.

What is the purpose of this study?

You are being asked to participate in this study because you have had a successful spinal cord stimulation (SCS) trial and are indicated for permanent implantation. SCS has been used for many years and has proven to be effective in the treatment of chronic, intractable pain. Leads are placed in the epidural space, which apply electrical stimulation to the spinal cord. Lead placement has historically been done under awake conditions, using direct feedback from the patient in order to define adequate paresthesia coverage. This could be stressful for the patient and predisposes them to movement, which can lead to decreased patient satisfaction, equipment migration, undesired stimulation effects, and treatment failure. Implantation under general anesthesia (non-awake) is potentially more comfortable for the patient and may carry less risk for revision.

The purpose of this study is to collect data necessary to demonstrate the safety and efficacy of non-awake implantation of SCS paddle leads compared to the awake procedure. This study is designed to evaluate whether non-awake placement reduces procedure time, complication rates, and/or revision rates while offering comparable paresthesia coverage as the awake procedure.

This study will be carried out at the following institutions using the technique as indicated (Awake versus Non-Awake). You will be assigned to the Non-Awake procedure here ate St. Luke's University Health Network.

- St. Luke's University Health Network (Non-Awake)
- Thomas Jefferson University Hospital (Non-Awake)
- Geisinger Medical Center (Awake)
- Milton S. Hershey Medical Center (Awake)

How many individuals will participate in the study and how long will the study last?

Approximately 50 patients will participate nationally. We hope to enroll approximately 20 patients at St. Luke's University Health Network. Your involvement in the study will last about 24 weeks.

What will I have to do during the study?

If you are willing to participate in the study, you will sign the informed consent. You will then be evaluated for eligibility, which will include a report of medical history, current medications, and completion questionnaires (described in detail below).

Questionnaires

You will be given questionnaires to complete on your own. It is important that you understand the meaning of all the words in the questionnaires, and ask any questions about the questionnaires if further explanation is needed. Below is a listing of questionnaires you will be asked to complete:

Short-Form McGill Pain Questionnaire (SF-MPQ-2)

The Short-Form McGill Pain Questionnaire version 2 (SF-MPQ-2) is a widely used scale used to measure the major symptoms of both neuropathic and non-neuropathic pain. This questionnaire consists of a set of 22 different pain descriptors. You will be instructed to indicate how accurately the descriptor word describes your pain on a scale ranging from 0 ('None') to 10 ('Worst Possible'). The questionnaire takes approximately 5-10 minutes to complete.

Pain Evaluation Form

You will be provided with a questionnaire at follow-up visits to complete to evaluate your pain relief from the device and rate your current, average, worst, and least pain.

EuroQol (EQ-5D) generic health index questionnaire

EQ-5D is a standardized instrument for measuring health outcome using a standard layout for the five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) of your health state.

Pain Location Form

The Pain Location Form includes a map of the body that is labeled with different numbered regions. You will be instructed to shade in or place an X in the area where you are feeling pain.

Paresthesia Coverage Form

The Paresthesia Coverage Form includes a map of the body that is labeled with different numbered regions. You will be instructed to shade in or place an X the area where you are feeling stimulation/paresthesia. You will also indicate which area(s) of pain relief have had the greatest improvement over your daily activities.

SCS Permanent System Implantation

You will be prepped for surgical paddle lead placement according to usual practice, including anesthesia and customary intraoperative monitoring.

Lead Placement for Awake Arm

Upon approximate lead positioning, you will be brought to a conscious sedated state while maintaining local anesthetic. Stimulation of the spinal cord through the paddle lead will be accomplished with an external pulse generator. You will be asked about your pain to determine paresthesia coverage of painful regions. Upon satisfactory coverage, the IPG will be implanted

per usual practice.

Lead Placement for Non-awake Arm

You will be maintained under general anesthesia for the full duration of the implant. Upon approximate lead positioning, EMG monitoring for SCS coverage of pain areas will be done. Stimulation is delivered through the lead by an external pulse generator. Upon satisfactory coverage, the IPG will be implanted per usual practice.

Postoperative Management and Instruction

The physician will provide normal standard of care after implantation of the system, including standard post-operative monitoring. Instructions for wound care and monitoring will be provided and you will be sent home for a 2-3 week recovery period to let any swelling and/or post-operative pain subside prior to activation of SCS system, unless otherwise determined by the installing investigator.

Device Activation

The permanent system device activation visit will occur approximately 2-3 weeks after permanent system implantation. At this visit, you will have your device programmed per usual practice. A map of paresthesia coverage will be collected, along with final programmed parameters, lead impedance, and device data. Any changes in medications will be noted, and you will be asked to complete the Patient Global Impression Form to assess your satisfaction with the permanent implant procedure.

Follow-up Visits

You will report to the office at the specified intervals below. Under the guidance of the Investigative team at each visit, SJM field representatives may assist with programming of your device as needed during the course of the study.

- 6 Week and 24 Month Visits
  You will be monitored for the safety and efficacy of the therapy, and the following will be collected/completed:
  - A map of paresthesia coverage along with programming parameters, lead impedance, and device data
  - Changes in medications
  - Pain metrics via self-reported pain relief, NRS, and SF-MPQ
  - Quality of Life (EQ-5D)

- Unscheduled Visit
  An Unscheduled Visit form will be used if you make an unscheduled office visit. The Healthcare Utilization (HCOR) form will be completed for all unscheduled visits.

What are the risks or discomforts involved?

There are no additional risks from the standard of care, and possible loss of confidentiality. However, measures will be taken to prevent loss of confidentiality as described below.

You should call the study doctor as soon as possible at 484-526-6000 if, during the course of this study, you develop any of side effects or symptoms. The study doctor has told you that if your condition worsens, if side effects become very severe, or if it turns out that being in this study is not in your best interest, you will be taken out of the study.

What are the risks to fetuses, infants and pregnant women?

Pregnant women will not be included this study because the effects of SCS to the mother, embryo, and fetus are unknown. To be in this study you and your partner must practice adequate birth control measures. The study doctor will discuss acceptable methods of birth control with you. If you are a woman of childbearing potential, you will have a pregnancy test before making a decision about being in this study. This requires either a urine test or that blood be drawn from a vein in your arm (1-2 tsp.) prior to the start of the study and according to study guidelines. The results of this pregnancy test will be made available to you prior to the start of the study.

If you become pregnant during the course of this study, you should notify the study doctor as soon as possible.

Are there alternatives to being in the study?

You do not have to participate in this study.

HIPAA Authorization: How will privacy and confidentiality (identity) be protected?

Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies you personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that you may see and review your St. Luke's University Health Network medical records at any time. However, in a research study, you may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If you join this study, the following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of St. Luke's University Health Network involved in this specific study, including the

Institutional Review Board (IRB), and your health insurance company (if necessary for billing for standard medical care). It may also be provided to other people or groups as follows:

- Researchers at Thomas Jefferson University Hospital, Geisinger Medical Center, and Milton S. Hershey Medical Center

Your PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- St. Jude Medical which is providing funds to St. Luke's University Health Network to conduct this research
- The Food and Drug Administration (FDA)
- With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:

Study data for analysis: Questionnaires, Medical History and medications, surgery and device information
Demographic data: gender, age, height, weight, ethnicity, marital status

If you develop an illness or injury during the course of your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study. Your PHI may be used/ disclosed indefinitely.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at:

Steven Falowski, MD
701 Ostrum Street, Suite 302
Bethlehem, PA 18015

If you quit the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

After your information is shared with others, like the sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose information about you

only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. When using the information in these ways, the sponsor may share it with other researchers, its business partners, or companies hired to provide research-related services. However, your name will never appear in any sponsor forms, reports, databases, or publications, or in any future disclosures by the sponsor.

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, this Web site will include a summary of the results. You can search this Web site at any time.

What if I am injured as a result of being in this study?

In the event that you experience a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or illness resulting to you that is directly caused by any procedure or treatment used in this study that is different from the treatment you would receive if you were not participating in a research study. If you are physically injured due to any procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. You should be aware that some costs may not be covered by insurance. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you receive a bill related to a research-related injury that seems wrong, please discuss it with the study doctor or research coordinator.

Will I benefit from being in this study?

You <u>may not</u> benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general.

Will I be paid for being in this study?

You <u>will not</u> receive payment for your participation in this study.

In addition, you will not be paid if inventions and/or patents are developed from the study results.

Will I be told about any new findings?

Anything learned during the study, beneficial or not, that may affect your health or your willingness to continue in the study, will be told to you and explained.

Disclosure of Financial Interest

The funding sponsor of this clinical study, St. Jude Medical, is paying St. Luke's University Health Network to conduct this study.

Are there costs related to being in this study?

Research Procedures

There are no investigational devices being used in this study, and all services will be billed to your insurance.

Standard Testing Procedures

Procedures, tests and doctor's charges resulting from being in the study that are considered standard of care will be billed to your health insurance carrier. These are charges that you would have whether or not you were participating in a research study. It is possible that your insurance company may deny payment. If that happens you may be responsible for some or all of these charges. All services are standard of care in this study.

If you receive a bill that you think is wrong, please discuss it with the study doctor or research coordinator.

Can I be removed from the study or quit the study?

Your decision to participate in this research study is entirely voluntary. You have been told what being in this study will involve, including the possible risks and benefits.

Your participation in this research project may be terminated by the study doctor without your consent for any reason that he/she feels is appropriate.

You may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting your ability to receive medical care at St. Luke's University Health Network.

If you withdraw from this study, you may continue treatment with your St. Luke's University Health Network doctor, or you may seek treatment from another doctor of your choice.

Should you decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	St. Luke's University Health Network Institutional Review Board	***484-526-4669***
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Steven Falowski or any co-investigator listed at the beginning of this form	***484-526-6000***

By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.

You affirm that you have read this consent form, and have been told that you will receive a copy.

You also authorize the use and disclosure of your health information to the parties listed in the HIPAA authorization section of this consent for the purposes as described.

_____
Your Name *(please print or type)*

_____ _____
Your Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date