INFORMED CONSENT TO PARTICIPATE IN A CLINICAL FEASIBILITY STUDY
Title of Study: CLINICAL FEASIBILITY STUDY OF THE IMPLANTABLE TIBIAL NERVE STIMULATOR

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INTRODUCTION

You have been invited to join a clinical feasibility study to evaluate the safety of an implantable tibial nerve stimulator (ITNS) and any effect it has on your medical condition. The device is investigational and not approved by the FDA for your medical condition.

This study is sponsored by Nine Continents Medical, the manufacturer of the ITNS. Before you decide if you want to be involved in the study, it is important that you read and understand this information. Be sure to ask questions about anything that is unclear. Your physician will answer your questions about the study, the device or any of the information being presented.

No study-related tests or procedures will be done before you sign this consent form.

PURPOSE AND BACKGROUND

The reason we are doing this research study is to look at the ITNS to see if it can help treat overactive bladder. This type of research study is called a "clinical feasibility study". A clinical feasibility study will help us understand basic safety and performance of the study device when used to treat overactive bladder. A small number of subjects will be included in this study. Since this is a clinical feasibility study, some risks are unknown and there is no guarantee that the device will help you or improve your condition. It is possible however that the device may help improve your condition.

The ITNS generates electrical pulses and sends them toward a nerve near the inside of your ankle, called the "posterior tibial nerve". This nerve carries signals upward to other nerves that affect bladder function. The ITNS has a built-in lithium cell, designed to power it for over 10 years in normal conditions. It has an electronic circuit to time and regulate the electrical pulses, and a flexible insulated wire to carry the pulses toward the nerve. Your physician will implant the ITNS under the skin, on the inside of the leg above the ankle.

This study is taking place in one clinic, and up to 10 patients will receive the ITNS.

PRIOR INFORMATION AVAILABLE ON THE DEVICE

This study is the first time that physicians will test the ITNS in patients.

WHO CAN PARTICIPATE IN THE STUDY

To find out if you meet all the requirements for this clinical feasibility study, your physician will ask you questions and check your medical records.

Before you decide to be in the study, be sure you understand all the information given and ask your physician any questions you may have about your participation in this study.

If you decide to participate in this study, you can sign this form, which will allow your physician to perform additional study-related tests to see if you are a good candidate for this study. Please understand that your consent is required in order for your physician to evaluate you further as a potential candidate for the study. You will not be actually enrolled into the study until your physician confirms that you meet all the criteria for inclusion in the study.

You may be considered for this study only if you:

1. Agree in writing to participate in this study (by signing this consent form).
2. Are at least 18 years of age.
3. Meet all eligibility criteria as assessed by your physician

STUDY PROCEDURE

Study related assessments

After your physician determines you are good candidate for this study, he or she will conduct study related assessments. These assessments include a medical history, physical examination, and routine lab tests. The physical examination will include a brief test of your response to electrical pulses, using a small acupuncture needle near your ankle. Your physician may also need to perform some other routine urology exams to confirm your diagnosis.

Your physician will also ask you to complete a diary at home to track your fluid intake, bathroom visits, and pad use, over at least three days. You will also need to complete a questionnaire about your bladder symptoms and general medical condition.

If the study related assessments confirm your diagnosis and your response to electrical pulses, then your physician will enroll you in the study and implant an ITNS in the clinic. If not, then your participation in the study will end at that time, without enrollment and without an ITNS implant.

General study procedures

Your health will be monitored and data will be collected for the study during the implant procedure at the clinic. You will return to the clinic for your physician to evaluate your health and your ITNS implant, at 4 weeks, 6 weeks, 19 weeks, and 26 weeks after implant. To test whether your symptoms changed with the ITNS implanted, you will complete another diary for at least three days, and the questionnaire; during the week before the 19-week visit. Your participation in the study will end after 6 months, but you will keep your ITNS implanted if it helps your condition. Otherwise your physician will remove your ITNS.

It could provide helpful data for the study if you complete your diaries for seven days instead of three, and if you complete additional diaries after your 6-week visit and before your 26-week visit. However, these additional procedures are optional, and whether or not you do them will not affect your care.

RISKS AND DISCOMFORTS

There might be unexpected risks from being in this type of clinical feasibility research study. This is because there may not be enough available data or experience with the study device. New

information from this research study may give the sponsor useful information to improve the device and procedure. This may help support future research studies with the study device. This research study involves the first human use of the study device.

Some risks in this study are similar to those associated with currently available devices used to treat overactive bladder with a permanent implant, including, but not limited to, infection, erosion, extrusion, damage to a nerve or a blood vessel, or pain at the implant site. The implanted device could move under the skin. Its electronics, battery, wires, or insulation could malfunction. There could be a reaction so that the implant's electrical pulses stop affecting the nerve. Any of these could require a medical or surgical procedure to correct, and they could prevent the implant from improving your symptoms. Even if none of these occurs, there is still a risk that the implant will not improve your symptoms.

Since this device is in its early phase of development, there may be other risks that are unforeseen at this time. Precautions will be taken to avoid harmful side effects as a result of participation in this study. Your physician will closely monitor your health status throughout the study.

If you are female, this procedure and/or treatments may involve unforeseeable risks to an embryo or fetus. If you are of child bearing age please consult your physician prior to consenting for this study.

Participation in the clinical study may interfere with standard of care treatment management, both during your participation in the study, and after you are no longer participating in the study. For example, you may not be able to receive an MRI scan for as long as the ITNS device remains implanted inside your body

RISK MITIGATION STRATEGIES

The sponsor has done the following things to reduce the risks to subjects.

The FDA has approved the use of this device in a clinical feasibility study.

Your study doctor was chosen to do this research study because he knows about your illness. Your study doctor has experience in treating overactive bladder with electrical pulses.

Your study doctor has been trained to use the study device for overactive bladder. The study doctor's training included using a laboratory model and other hands-on training.

Your study doctor and any needed site personnel have been trained to the research study protocol. This training includes the design and proper use of the study device. It includes all patient follow-up requirements.

Every research site must get approval from an Institutional Review Board (IRB). This group of people reviews the protocol and the informed consent to make sure the research study is ethical and your safety and welfare rights are protected.

If a problem occurs with the study device, your physician can remove it, and he can continue to treat you with approved devices and procedures.

POSSIBLE BENEFITS IF YOU JOIN THIS STUDY

It is possible that there may be no direct benefit to you as a consequence of participating in this study. However, your participation in the study may help the sponsor collect information to optimize the design, function or procedure of the ITNS to help other patients in the future. There

might be potential benefits to you. Potential benefits of the ITNS may include significant improvement of overactive bladder symptoms.

OTHER TREATMENTS AVAILABLE

Alternative therapies for your medical condition may include stimulation of your posterior tibial nerve at regular clinic visits (PTNS), implantation of different device that stimulates a nerve near the spine, or regular Botox® injections in your bladder. Your physician will discuss your situation with you and will recommend the best treatment for you, including how the experimental therapy would differ from the standard of care.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary. You have the right to refuse to participate in this study. If you decide to participate, you can change your mind and choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services you may receive from this clinic or hospital. You do not need to specify the reason for which you withdraw. If you wish to participate, you will be asked to sign this form. Please take time to read this information carefully and to discuss it with your family, friends, and physician before you decide. If you decide to stop taking part in this study, you must tell your study physician. Your study physician can discuss with you whether any testing or follow-up may need to be done for your safety.

Your physician or the sponsor can remove you from the study at any time without your approval. If your participation is stopped, you may be asked to undergo a routine medical exam and/or blood testing for safety reasons. Your physician may need to remove your ITNS. Any patient who is withdrawn from the study for any reason may not re-enter the study at any time.

CONFIDENTIALITY OF STUDY RECORDS AND MEDICAL RECORDS

Information collected for this study is confidential. Access to your personal medical information will be limited to the purposes of collection and processing information necessary for the completion of this study.

Your privacy is important. You will only be identified in the study by a code. This number is not derived from any of your personal information. Should results of this study be published (in a medical journal), you will not be identified through your name or other personal information. Data collected and reported to the sponsor for this study are the property of the sponsor. Your study records are just like hospital records. They may be subpoenaed by court order or may be inspected by federal regulatory authorities.

PROTECTED HEALTH INFORMATION

Who may use and disclose information about you?

The people who may use your Private Health Information include your study physician Dr. Sethi and his/her staff; the Western Institutional Review Board and its staff; legal counsel; audit and compliance staff; and other people who need to see the information to help the study or make sure it is being done correctly. These people may disclose your Private Health Information to staff of the entities listed in the next section.

Who may see your health information?

Your Private Health Information may be disclosed to people associated with the following entities:

- Government agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration
- The sponsor of the study and organizations that the sponsor may contract with for the study. The name of the sponsor is Nine Continents Medical.

Why will your information be used and disclosed?

Your information will be used and disclosed to carry out the study and to evaluate the results of the study.

Your information may also be used to meet the reporting requirements of government agencies.

Information about the study will be posted on ClinicalTrials.gov, but your Private Health Information will not be disclosed there.

Can you decide not to authorize the use and disclosure of your Private Health Information?

Yes. You do not have to authorize the use or disclosure of your Private Health Information. However, if you do not sign this authorization, then you cannot participate in the study.

Can you revoke your authorization?

Yes. You may revoke your authorization to allow your Private Health Information to be used or disclosed at any time by sending a written notice to the principal investigator, Parminder Sethi, M.D., Pacific Urology, 5201 Norris Canyon Rd., Suite 140, San Ramon, CA 94583.

If you revoke your authorization, you will be withdrawn from the study and no health information about you will be gathered after that date. However, information gathered before that date may be used or disclosed if it is needed for the study or any follow-up for the study.

Is your health information protected after it has been disclosed to others?

If your health information is disclosed to someone who is not required to follow the Privacy Rule, then that information may no longer be protected, and it may be used or disclosed without your permission.

The sponsor of the study, Nine Continents Medical, the Investigator and all involved third parties have agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act (“HIPAA”).

Can you see your health information?

Yes. You may see and copy your information after the study ends.

Does your authorization have an expiration date?

Your authorization to use and disclose health information will continue until the end of the study and any necessary data analysis follow-up activities for the study. However, the information and data that is collected during the period that your authorization is effective can continue to be used and disclosed after your authorization has expired.

STUDY RELATED INJURY

If physical injury happens to you because of your involvement in this clinical feasibility study, medical treatment will be available, if appropriate, at the hospital. You will not be financially liable for the costs of such treatment. Contact your physician if you experience a study related injury.

RIGHTS AND COMPENSATION

You will not be paid to participate in this study, other than reimbursement for your time and travel costs for required study visits, which your study physician will discuss with you. Your hospitalization and procedures will be considered part of your routine medical care. By signing this form, you do not give up any of your legal rights and you do not release the study physician or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study. You will not be charged for any study procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your medical plan and/or by the study sponsor, Nine Continents Medical.

WHOM YOU SHOULD CONTACT IF YOU HAVE QUESTIONS

If you have any questions about taking part in this study, or if you think you may have been injured because of the study, call Parminder Sethi, M.D. at (925) 937-7740**.**

If you have any questions about your rights as a study patient, you can call the Western Institutional Review Board at (360) 252-2500.

You should also inform your study physician if you have been injured or hospitalized for any reason during the study.

PATIENT'S STATEMENT

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact Parminder Sethi, M.D. at (925) 937-7740**.**

I understand that my participation in this clinical feasibility study is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be otherwise entitled. I understand that there might be other treatment alternatives for me. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. If I have any questions about my rights as a patient in this study I may contact: Chairperson, Western Institutional Review Board, 1019 39th Avenue SE, Suite 120, Puyallup, WA 98374-2115.

By signing this consent form, I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of study participant: _____

Printed name of study participant: _____

Date signed: _____

Signature of legal representative: _____

Printed name of legal representative: _____

Date signed: _____

Signature of person discussing consent: _____

Printed name of person discussing consent: _____

Date signed: _____

Signature of investigator: _____

Printed name of investigator: _____

Date signed: _____