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Northwestern University
Department of Obstetrics and Gynecology
Consent Form and HIPAA Authorization for Research

PROTOCOL TITLE: Sacral Neuromodulation for Dual Incontinence (SaNDI): Ultrasound and Afferent Nerve Sensation Assessment
PRINCIPAL INVESTIGATOR: Kimberly Kenton, MD, MS
SUPPORTED BY: American Urogynecologic Society – Pelvic Floor Disorders Foundation Grant

Introduction
You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

Conflict of Interest Disclosure
The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

What is the reason for doing this study?
The purpose of this study is to learn more about nerve and muscle function in patients with dual incontinence (both Urinary Incontinence and Fecal Incontinence) and also to learn how Sacral Neuromodulation (SNM) affects the nerves of patients with dual incontinence. By learning more about nerve function in patients with dual incontinence before and after SNM treatment, we hope to find a way to screen patients before treatment with SNM to make sure this treatment will be effective for them. We also hope to learn how urethral and anal sphincter anatomy in patients with dual incontinence changes after treatment with SNM. Lastly, we hope to assess the quality of sexual relationships in women with dual incontinence and their male partners and identify specific areas of dysfunction that are common in patients with dual incontinence.

You are being asked to participate because you have dual incontinence and are planning to undergo placement of a Sacral Nerve Modulator (SNM). SNM is a standard of care treatment and enrolling in this study is not required for this or other treatment options. This consent form describes the additional research procedures which will be performed if you wish to participate in the study.

How many people will take part in this study?
The study investigators hope to enroll 15 subjects in this study.

What will you do if you choose to be in this study?
If you consent to participate in this study, you will undergo Current Perception Threshold (CPT) testing and fill out two additional questionnaires at your baseline visit with your physician. If you are implanted with the InterStim device (the device that delivers the Sacral Neuromodulation) you will undergo CPT Testing again at your 3 month follow up visit and also fill out two

additional questionnaires. If you are **not** implanted with the Interstim device, you will **not** undergo a second round of CPT testing or fill out questionnaires.

The questionnaires will ask about the symptoms you may experience related to fecal incontinence and how they affect your quality of life, and also about the quality of your sexual relationship.

In addition, if you have a male partner that you are sexually active with, your partner will be asked to fill out a questionnaire at your baseline visit and at your 3 month follow up visit. He will have to come to your baseline appointment to fill out a consent form to participate in the research. If you do not have a male partner or are not sexually active, you are still eligible to participate in this research study. After 3 months, your participation in this study will be complete.

	Baseline Visit	**3 Month Follow-Up Visit**
CPT Testing	X	X
GRISS Questionnaire	X	X
FiQOL Questionnaire	X	X

Please note that CPT testing is for research purposes only. Sacral Nerve Modulation is a standard of care treatment, and this treatment option is available regardless of if you choose to participate in this study or not. SNM treatment and other treatment options are available without enrolling in this study, and any procedures proposed solely for research purposes are optional.

What is CPT Testing?

CPT testing involves the use of a sNCT device, which is a portable battery-operated machine which will stimulate your nerves via an electrical stimulation. Electrodes will be placed via a catheter in to your urethra and also in your rectum, and the electrical current will be increased gradually until you feel the onset of tingling, buzzing, or warmth at the site of the electrode. The electrical current will then gradually decrease until you feel no sensation of stimulation. The procedure will then be repeated where you will be asked to hold the test button to increase the stimulus intensity above your sensory threshold (above the point where you can feel it) until the device automatically shuts off or until you release the test button to stop the test in the event that electrical stimulus becomes painful. It is **not** necessary that you experience pain in order for the sNCT device to automatically shut off. The testing will require approximately 60 minutes.

What are some of the possible risks and discomforts?

There are no known major risks associated with the mild electrical stimulation administered for the CPT testing. Its output via a battery is designed to prevent electrical shock. You can choose to stop the test at any time during testing. You may experience some discomfort in your urethra or rectum where the electrodes are placed. Another risk is the transfer of germs between participants. To mitigate this risk, all equipment that comes into contact with participants will be sterilized.

Another risk is that we will be collecting your questionnaire responses in a secure electronic database. Your name and other identifying information will always be kept separate from the database. Only the doctors caring for you and the study staff will be able to see your information. We will take every precaution to protect your privacy.

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

You should discuss these risks with the study doctor, or your regular doctor. There may be other risks that we cannot predict. Your condition may not get better or may become worse during this study.

What do I need to know about reproductive health/sexual activity if I am in this study?
If sexually active, you should use an effective method of birth control while participating in the trial. Barrier contraceptives (condoms or diaphragm) with spermicide, intrauterine devices (IUD's), hormonal contraceptives, oral contraceptive pills, surgical sterilization, and complete abstinence are examples of effective methods. If you or your partner become pregnant while enrolled in the study, it is important that you tell your study nurse/doctor immediately. You may have to end your participation in the study.

If you are considered to be postmenopausal, you are not required to use contraception while in this study. Rarely, women considered to be postmenopausal become pregnant. If you suspect that you become pregnant while enrolled in the study, it is important that you tell the study nurse/doctor immediately.

What are the Possible Benefits for Me or Others?
You are not likely to have any direct benefit from being in this research study. Taking part in this study may help scientists to better understand the changes that take place in pelvic neurons and muscles in patients with dual incontinence and also identify potential factors that will improve the success of SNM treatment.

What other procedures or courses of treatment might be available to me?
You may choose not to participate in this research study.

Are there any financial costs to being in this study*?*
There will be tests and procedures that are done only for this study and other tests and procedures that are part of your conventional medical care (not part of the research).

- The cost of your conventional medical care will be billed to you or to your health insurance company in the usual way. However, some health insurance plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

Will I receive payment for participation in this study?
You will receive a $50 Prepaid gift card gift card after undergoing CPT testing and filling out surveys at your initial baseline visit. If you are implanted with InterStim, you will receive an additional $50 Prepaid gift card gift card for undergoing CPT Testing and filling out surveys at your 3 month follow up visit. If you are **not** implanted with InterStim, you will **not** undergo a second round of CPT testing and surveys, and will **not** receive the second $50 Prepaid gift card gift card. If you withdraw from the study, you will be paid for the portions that you completed.

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

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If you become ill or get an injury or illness as a result of study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly.

Kimberly Kenton is the person in charge of this research study. You can call her at (312) 695-6600 during Monday through Friday, from 9am to 5pm. Outside of business hours, or on nights and weekends, you may call (312) 926-4747, which is an answering service that will put you in contact with our physician that is on-call.

You can also call Maggie Mueller at (312) 472-6455 with questions about this research study. You can also call the Research Coordinator, Alexis Siurek at (312) 695-7748 with questions about this research study.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

Your participation in this study may be stopped by the investigator without your consent if:

- If you are not eligible for permanent device implantation
- You do not follow the study instructions
- Your medical condition changes and your doctor feels it is in your best interest to stop the study or for administrative reasons
- You do not later consent to any future changes that may be made in the study plan
- Or for any other reason

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical and research record
- Results of physical examinations
- Records about phone calls
- Records about study visits
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Insurers or third party payers

During this study you may be coming to the Northwestern Medical Faculty Foundation (NMFF) clinical offices for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMFF computer system. When a clinical exam or lab is done by NMFF or one of its employees for the purpose of this research study, that information will be kept in both NMFF's clinical records and in the study records.

The following groups of people may give the researchers information about you:

- All current and previous health care providers, including but not limited to the Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office] **.**

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),
- Clinical affiliates, including but not limited to Northwestern Medical Faculty Foundation (NMFF) and Northwestern Memorial Hospital (NMH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- American Urogynecologic Society, who is sponsoring the study, and that organization's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- A Northwestern University database "REDCap" (Research Electronic Data Capture) will be used for building and managing online data capture for this research study. This is a secure, web-based application that only the PI and study coordinator will have access to.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or presentations at scientific meetings.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:

  PI's Name: Kimberly Kenton, MD

  Institution: Northwestern Medical Faculty Foundation

  Department: Obstetrics and Gynecology

  Address: 676 N St. Clair Street, Arkes Building – Suite 950. Chicago, IL 60611
- Unless you revoke your consent, it will not expire.
- If you "take back" (revoke) your consent to use any blood or tissue taken for the study, the Principal Investigator will make sure that these specimens are destroyed or will make sure that all information that could identify you is removed from these samples.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above. A copy of the consent form will be provided to me after I sign it.

A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

_____ _____

Subject's Name (printed) and Signature Date

_____ _____

Name (printed) and Signature of Person Obtaining Consent Date