INFORMED CONSENT AND RESEARCH AUTHORIZATION

Study Title: InterStim Implantation Rate Following Percutaneous Nerve Evaluation With Fluoroscopy versus Without

Principal Investigator: Sean Francis MD

Co-Investigators: Kate Meriwether MD, Ankita Gupta MD, MPH (Fellow),
James R. Stewart DO(Fellow), Deslyn Hobson MD (Fellow)
University of Louisville, Dept OB/GYN
Division of Female Pelvic Medicine & Reconstructive Surgery
550 South Jackson Street
Louisville, KY 40202

Study Centers: University of Louisville Hospital (ULH) Outpatient Surgery Center at HCOC

IRB #: 15.0034

Phone number for subjects to call for questions: 502 588-4400

Revised Consent dated April 23, 2018

Introduction and Background Information

You are invited to take part in a research study because you have urinary problems and have elected to undergo a routine test called Percutaneous Nerve Evaluation (PNE) for the treatment of your urinary symptoms. This test will involve placing 2 temporary thin wires through the skin above your tailbone to stimulate the nerves in your pelvis that control the bladder. This procedure will be done at the HCOC Outpatient Surgery Center. A local anesthetic (numbing medicine) will be injected in the area where the wires will enter your skin. Depending on which group you are randomized (assigned) to, you may or may not have a type of x-ray called fluoroscopy done at the time of your PNE to show that the lead wires are in the correct location.

The study is being conducted under the direction of Dr. Sean Francis MD and Dr. Ankita Gupta at the University of Louisville**.** About 100 subjects will be invited to take part in this research.

Purpose

The purpose of this study is to see if placing the test wires with the help of fluoroscopy (x-ray), makes it more likely for someone to follow through with getting the permanent nerve stimulator implanted when compared to patients who have the test wire placed without the help of fluoroscopy.

Procedures

Your participation will start at the time of consenting for the study during your first office visit or on the day of your procedure and will end 3 months after you undergo PNE. There will be no additional study related visits during the 3 months after the procedure.

If you agree to participate in the study, you will be randomized to placement of the PNE with or without fluoroscopy in a process similar to the flipping of a coin. It is our standard practice to perform this procedure without the use of fluoroscopy. The fluoroscopy will be used to confirm correct placement of the leads during your procedure.

Should you have 50% or greater improvement in your urinary symptoms in this time period, then you will be eligible to have the permanent sacral nerve stimulator lead and battery (InterStim), implanted in a separate procedure.

Potential Risks

Risks to PNE include bleeding, bruising, infection, and/or pain or discomfort at the site of the wire insertion, movement of the wires and you may feel a temporary tingling sensation.

Risk of fluoroscopy: The amount of time exposed to radiation during fluoroscopy would be similar to that of standard x-rays.

In addition, you may suffer harms that we have not seen before.

Possible Pregnancy Risks

Pregnant women are excluded from participation in this study as they are not candidates for sacral neuromodulation.

Benefits

You may not benefit by participating in this study. The information collected may not benefit you directly; however, the information may be helpful to others.

Alternatives

Instead of taking part in this study, you could choose to decline participation. Participation is completely voluntary. If you choose not to participate, you could have this procedure performed without being in the study.

Research Related Injury

If you are injured by being in this research study, the study doctor will arrange for you to get medical treatment. The sponsor, the study site, or your study doctor has not set aside money to pay for treatment of any injury. You and your insurance will be billed for the treatment of these injuries. Before you agree to take part in this research study you should find out whether your insurance will cover an injury in this kind of research. You should talk to the study doctor or staff about this. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up

your legal rights by signing this form. If you think you have a research related injury, please call Dr. Ankita Gupta at 502 588-4400 or you can email Dr. Gupta at ankita.gupta@louisville.edu

Compensation

You will not be compensated for your time, inconvenience, or expenses while you are in this study.

Costs

You or your insurance company will be billed for all office visits, tests, medications and procedures that are part of your routine medical care and this research study. You will be responsible for paying your co-pay that is associated with any office visit, test, medication or procedure. Some insurance companies will not pay for medical bills for people who participate in a research study. It is your responsibility to find out what costs, if any, your insurance company will cover before taking part in the study. If you need help finding out what your insurance company will cover, please ask your study doctor for assistance. If your insurance company does not pay for your bills associated with this study, you will be responsible for paying them."

If you are injured, there will be additional costs to you for participating in this research study.

HIPAA Research Authorization

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). Examples of PHI are your name, address, and birth date together with your health information. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this research study. Your PHI may not be used or shared without your agreement, unless it meets one of the HIPAA exceptions.

State and federal privacy laws protect your health information. In most cases, health information that identifies you can be used or shared by the research team only if you give your permission by signing this form.

If you sign this form your health information will be used and shared to answer the research questions described above and to make sure that the research was done correctly. The time period when information can be used or shared ends when all activities related to this study are completed.

Your access to your health information will not be limited during this study.

You do not have to sign this form. If you do not sign this form you may not participate in the study and health information that identifies you will not be shared with the research team.

Site(s) where health information about you will be used or shared for this research:

In our research, the research team will look at and may share information about you and your health. Federal law requires that health care providers and researchers protect the privacy and security of health information that identifies you. We may ask for your health information from the following:

Affiliated Sites:

University of Louisville
University of Louisville Health Care Outpatient Center (HCOC)
University of Louisville Hospital (ULH) Outpatient Surgery Center at HCOC

Faculty Practice Group Sites:

University of Louisville Physicians (ULP)

Protected health information (PHI) that will be used or shared for research

- Records of your operation
- Height and weight
- Medical progress notes
- Diaries and questionnaires

Revocation of Research Authorization
You may cancel the permission you have given to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you cancel your permission:

- We will stop collecting information about you.

- You may not withdraw information that we had before you told us to stop.
    - We may already have used it or shared it.
    - We may need it to complete the research.
- Staff may ask your permission to follow-up with you if there is a medical reason to do so.

To cancel your permission, you may be requested to complete a written "Revocation of Research Authorization" form located at the end of this document. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects Protections Program Office website (http://louisville.edu/research/humansubjects/subject-information).

Confidentiality

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

Your information may be shared with the following:

- The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
- The local research team
- People who are responsible for research and HIPAA oversight at the institutions where the research is conducted

- People responsible for billing, sending and receiving payments related to your participation in the study
- Government agencies, such as:
    - Office for Human Research Protections
    - Office of Civil Rights
    - Food and Drug Administration

Security

Your information will be stored securely in a locked file cabinet and in a password protected, encrypted (using a special code for security) laptop computer with restricted use.

Voluntary Participation

Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won't be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop

taking part, you won't be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study.

Termination

Your study doctor or the study sponsor has the right to stop this study at any point. Your study doctor may take you out of this study with or without your okay.

Participation in Other Research Studies

You may take part in this study if you are currently in another research study. It is important to let your doctor know if you are in another research study.

Contact Persons

If you have any questions, concerns, or complaints about the research study, please contact Dr. Ankita Gupta at 502 588-4400 or ankita.gupta@louisville.edu

Research Subject's Rights

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You may discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has approved the participation of human subjects in this research study.

Concerns and Complaints

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call the toll free number 1-877-852-1167. This is a 24-hour hot line answered by people who do not work at the University of Louisville.

Acknowledgment and Signatures

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights to which you are entitled by signing this informed consent document.

You will be given a copy of this consent form to keep for your records.

_____	_____
Subject Name (Please Print)	Signature of Subject Date Signed
_____	_____
Printed Name of Legal Representative (if applicable)	Signature of Legal Representative Date Signed
_____	
Relationship of Legal Representative to Subject	
_____	_____
Printed Name of Person Explaining Consent Form	Signature of Person Explaining Consent Form (if other than the Investigator) Date Signed
_____	_____
Printed Name of Investigator	Signature of Investigator Date Signed

---

List of Investigators:	Phone Numbers:
Sean Francis MD	502 588-4400
Kate Meriwether, MD	502 588-4400
Deslyn Hobson, MD	502 588-4400
James R. Ryan, MD	502 588-4400
Ankita Gupta, MD	502 588-4400

IRB # 15.0034: InterStim Implantation Rate Following Percutaneous Nerve Evaluation With Fluoroscopy versus Without

REVOCATION OF AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR HEALTH INFORMATION FOR RESEARCH

PI Address: Dr Sean Francis
University of Louisville
550 South Jackson Street, 1st Floor
Louisville. KY 40202 502 561-7260

Return To:

OR

Institutional Review Board
MedCenter One, Suite 200
501 E. Broadway
Louisville, KY 40202

Do not sign this letter unless you are withdrawing from this research. You will be sent confirmation that this notice was received.

To Whom It May Concern:

I would like to discontinue my participation in the research study noted above. I understand that health information already collected will continue to be used as discussed in the Authorization I signed when joining the study.

Your options are (***choose one***):

☐ **Withdraw from Study & Discontinue Authorization:**
Discontinue my authorization for the future use and disclosure of protected health information. In some instances, the research team may need to use your information even after you discontinue your authorization, for example, to notify you or government agencies of any health or safety concerns that were identified as part of your study participation.

☐ **Withdraw from Study, but Continue Authorization:**
Allow the research team to continue collecting information from my personal health information. This would be done only as needed to support the goals of the study and would not be used for purposes other than those already described in the research authorization.

_____ _____
Printed Name and Signature of Subject Date Signed

_____ _____
Signature of Subject's Legal Representative (if subject is unable to sign) Date Signed

_____ _____
Printed Name of Subject's Legal Representative Birthdate of Subject

_____
Relationship of Legal Representative to Subject

_____ _____
Subject's Address Subject's Phone Number

Optional:

I am ending my participation in this study because:

_____

_____