**TITLE OF RESEARCH STUDY: Lidocaine patches prior to percutaneous nerve evaluation**

**Introduction and Background Information**
You are invited to take part in a research study about lidocaine patches prior to Percutaneous Sacral Nerve Evaluation (PNE). The study is being conducted under the direction of Dr. Stacy Lenger, MD at the University of Louisville**.** About 34 local participants will be invited to take part in this research

**Why is this study being done?**
The purpose of this study is to determine if a lidocaine patch applied to the skin decreases pain from the PNE procedure. Lidocaine is the numbing agent commonly used during this procedure, and in other similar procedures, to reduce discomfort. Typically this numbing agent is injected beneath the skin and into the tissue at the site of this procedure. The lidocaine patch is another route of delivery of lidocaine – which can also be used to decrease skin discomfort.

**What will happen if I take part in the study?**
Your participation in the study will involve undergoing your planned PNE procedure, however, you will present 30 minutes prior to your planned procedure time and have a patch placed on your lower back. You will be randomized to either receive a patch containing lidocaine or a "placebo" patch which will not contain lidocaine. Your patch will be randomized between these two interventions. Randomization will occur by a procedure similar to flipping a coin – with you having an equal chance of being in either group. All participants will receive injectable lidocaine per standard of care as well. Your participation in this study will last for up to 3 months after a possible stage II sacral neuromodulation procedure.

Your urinary frequency prior to the procedure will be recorded. Before and after the procedure visual analog scale (VAS) pain score will be collected. At the completion of the PNE procedure the total amount of injectable lidocaine used, the site of stimulation for the PNE procedure, the amplitude of stimulation felt with the procedure, and a satisfaction scale with the procedure will be collected. 1 week after the procedure you will be seen for evaluation related to your PNE procedure per standard of care. At that 1 week office visit any adverse events, a satisfaction score, the number of days with successful stimulation, the amplitude of the stimulation felt, and your bladder/fecal diary will be collected. At that 1 week visit and thereafter you will undergo standard of care management of your urinary or fecal incontinence. Your data will again be accessed at 3 months post-PNE procedure via the electronic medical record to determine what interventions you have since undergone for this condition since the completion of the PNE procedure. You will not be contacted for the collection of this 3 month information.

**What are the possible risks or discomforts from being in this research study?**
The following details the known risks related to this research and how often they may occur.

- Uncommon: discomfort over the area the lidocaine patch was placed
- Rare: Allergy to adhesive bandage or lidocaine

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In addition, you may suffer harms that we do not anticipate

**What are the benefits of taking part in the study?**
You may or may not benefit personally by participating in this study. The information collected may not benefit you directly; however, the information may be helpful to others.

The possible benefits of this study include reduced pain with the procedure

**Will I be paid?**
You will not be paid for your time, inconvenience, or expenses while you are in this study.

**What are the Costs?**
You will not be billed for the study drug (lidocaine patches) or placebo (athletic tape) in this study.

You or your insurance company will be billed for all office visits, tests, additional 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 may be additional costs to you for participating in this research study.

**What other choices do I have if I do not take part in the study?**
Instead of taking part in this study, you could choose to:

- Undergo PNE procedure with the standard of care use of injectable lidocaine for discomfort
- Undergo PNE procedure with use of lidocaine patch and injectable lidocaine for discomfort

## What if I get injured on the study?

- 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 your study doctor (Stacy Lenger: (502)5887663)

**Information Available on ClinicalTrials.gov**
A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. The website will include a summary of the results of the clinical trial

**How will my information be protected?**
The data collected about you will be kept private and secure by the password protected and secure RedCap program.

**What information will be collected, used, or shared?**
If you sign this form, the research team working on this study will use and/or share your health information to answer the research questions for this study, and to make sure that the research was done correctly. They may also collect other information including your name, address, date of birth, medical history, and other information from your medical records from this institution and other institutions involved with this research, as well as from your other healthcare providers (which may include information about HIV status, drug, alcohol or sexually transmitted disease treatment, genetic test results, or mental health treatment). Once your information leaves your medical record, it may no longer be protected by HIPAA.

**Who will see, use or share the information?**
The people who may request, receive, or use your private information include the researchers and the study team. We may also share your information with other people, for example, if needed for your clinical care, for the research study activities, or for regulatory/compliance functions.

Additionally, by signing this form, you give permission to the research team to share your information with others outside of the University of Louisville. This may include the sponsor of the study and its agents or contractors, those who provide funding to the study, outside providers, study safety monitors, government agencies, other sites in the study, data managers, and other agents and contractors used by the study team. If applicable, your information may also be shared as required by law (for example, to collect or receive information for reporting child abuse or neglect, preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.)

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee this. Those who receive your information may not be required by federal or state privacy laws to protect it and may share your information with others without your permission.

**How long will information be used or shared?**
The time period when information can be used or shared ends when all activities related to this study are completed.

**May I review or copy the information obtained from me or created about me?**
Some information collected about you only for this research study may be kept in a research study record separate from your medical record, and some research information may also be part of your medical record. You will not have access to this research information until the end of the study. However, it will be available to your physicians if needed for your care.

**Will my information be used for future research?**
Your data will not be stored or shared for future research.

**Can I stop participating in the study at any time?**
Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may change your mind and stop taking part at any time. You will not be penalized or lose any benefits for which you qualify.

**Who can I contact for questions, concerns and complaints?**
If you have any questions about your rights as a research participant, you may call the Human Subjects Protection Program Office at (502) 852-5188. You may discuss any questions about your rights as a research participant, in private, with a member of the Institutional Review Board (IRB). 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 participants in this research study.

If you have any questions about the research study, please contact Rodger Rothenberger, MD: (502)5887663

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call this 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 document tells you what will happen during the study if you choose to take part. Your signature and date indicate 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 though you are providing your HIPAA authorization as outlined in this informed consent document. You will be given a copy of this consent form to keep for your records.

| _____ | _____ | _____ |
|---|---|---|
| Printed Name of Participant | Signature of Participant | Date Signed |
| _____ | _____ | _____ |
| Printed Name of Person Explaining Consent (PEC) | Signature of PEC (if not an investigator) | Date Signed |
| _____ | _____ | _____ |
| Printed Name of Investigator (PI, Sub-I, or Co-I) | Signature of Investigator (PI, Sub-I, or Co-I) | Date Signed |

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24 hour phone number for participants to call for questions: (502) 588-7660
Investigator(s) name, degree, phone number, University Department, & address:
Dr. Stacy Lenger, MD
Department of Obstetrics, Gynecology & Women's Health
Division of Female Pelvic Medicine and Reconstructive Surgery
550 South Jackson Street
Louisville, KY 40202

Site(s) where study is to be conducted:

- University of Louisville Hospital
- UofL Physicians – Urogynecology; Springs Medical Center Office
- UofL Physicians – Urogynecology Associates; 1900 Bluegrass Ave. Louisville, KY 40215