University of Pittsburgh

SCHOOL OF MEDICINE
Department of Obstetrics, Gynecology and Reproductive Sciences

UNIVERSITY OF PENSYLVANIA RESEARCH SUBJECT
INFORMED CONSENT and HIPPA AUTHORIZATION FORM

TITLE: NeurOmodulaTion for Accidental Bowel LEakage (NOTABLE)

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Please read this consent form carefully and take your time making your decision. The research staff will explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. This consent describes important information about the study treatments, including possible risks and benefits to you, the number of study visits, and the estimated amount of time it will take you to complete questionnaires and study forms, as well as possibly uncomfortable exams. This study requires participants to report information about their bowel habits using an app that is downloaded on a smartphone. We will ask for your permission to download the app on your phone. If you do not own a smartphone and you are eligible to participate in the study, a phone will be loaned to you for use in the study. Additional details are described later in this consent document.

This study was developed by scientists in the Pelvic Floor Disorders Network (PFDN), which is supported by grants from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH). None of the researchers will receive a direct payment or increase in salary for conducting this study. Please tell the study doctor or study staff if you are taking part in another research study.

A description of this clinical trial is available on the Internet at http://www.ClinicalTrials.gov, as required by U.S. law. At the end of the study, ClinicalTrials.gov will include a summary of the results. You can search this website at any time.

Why is this research being done?

Many women suffer from accidental bowel leakage or leakage of stool from the rectum. Investigators in the PFDN are interested in learning more about women with this condition and new treatments for this condition.

One new treatment for accidental bowel leakage is neuromodulation. Neuromodulation involves stimulating nerves to change how the body functions. Percutaneous Tibial Nerve Stimulation (PTNS) is one form of neuromodulation. PTNS uses mild electrical pulses to stimulate a nerve at the ankle (the tibial nerve). This nerve sends messages to your spinal cord, bowel, and rectum that may help control bowel function, including accidental bowel leakage. During PTNS, a very thin needle is placed into the skin above your ankle. This needle is attached to a battery-powered stimulator which sends mild electrical pulses to the tibial nerve for about 30 minutes. The electrical pulses cause a tingling in your foot; this should not be uncomfortable. The needle is removed after 30 minutes. This stimulation treatment is repeated every week for 12 weeks.

PTNS is an approved treatment for men and women who have accidental urine leakage. Small studies have shown that PTNS also reduces accidental bowel leakage. PTNS for accidental bowel leakage is experimental since it has not been approved by the Federal Drug Administration (FDA).

This study will compare PTNS to a 'sham' stimulation in women with accidental bowel leakage to learn if PTNS is better than sham at preventing accidental bowel leakage. The sham stimulation will provide a similar sensation of tingling in the foot, but it will not stimulate the tibial nerve. A sham treatment is also known as placebo.

This study will use an electronic bowel diary that is an app downloaded onto a smartphone. The phone diary was selected because it is more accurate and generally convenient than a paper diary. Additionally, the phone app bowel diary will enable the study team to send reminder notifications to your phone twice daily to help you remember to report all your bowel events (bowel movements and leakage episodes). The notification will appear as a pop-up bar at the top of the phone screen which will disappear shortly after appearing. To protect your privacy, the wording used in the pop-up bar is "Please review today's data." The app includes 3 questions about your bowel movement or accident and uses very little space on your phone. We estimate that it will use 0.01 GB, but may vary by phone type (iOS and Android). If your phone is connected to Wi-Fi, the app will not use your phone's data plan. If you are not using Wi-Fi and are instead using your phone's data plan, we estimate that the bowel diary app will use about 0.000015 GB of data per month. This estimate is based on 10 bowel movements or accidents per day being recorded in the bowel diary app. The participant identification number assigned to you for the study and the answers to the 3 questions about a bowel event will be sent from your phone to the research team. No other information, such as your name, phone number, contacts, or location, will be sent from your phone. After the study, we will provide you instructions on how to remove the mobile app from your device. If you are unwilling to download the bowel diary phone app onto your personal smartphone, you will not be able to participate in

this study.

Who is being asked to take part in this research study?
You are being asked to take part in this research study because you have accidental bowel leakage that has not gotten better after you have tried other treatments, such as exercises that make the muscles in your pelvis stronger or medications which make the stool less watery (like Imodium or loperamide).

About 359 women will be asked to participate in the NOTABLE study at 7 PFDN centers in the United States and about 50 women will be enrolled from the University of Pittsburgh / Magee-Womens Hospital.

What procedures will be performed for research purposes?
Participation in this study is completely voluntary. If you choose to be in this study, you will be asked to sign this consent. If you choose not to participate in this study, you may continue to receive care from your doctor.

This study is a little over 1 year long and has three parts. You may or may not be eligible to do all 3 parts.

1. **Run-In Phase.** This is a pre-study phase during which we will determine whether you are eligible to participate in the study. The Run-In Phase will be 4 weeks long. In Week 1 and Week 4, you will be asked questions about your accidental bowel leakage symptoms. You will also be asked to fill out a diary for 7 days to track information about your bowel habits. If you own a smartphone, we will ask for your permission to download an app which will allow you to complete the bowel diary on your smartphone. The diary will be done at the start of the Run-in Phase (Week 1) and at the end of the Run-In Phase (Week 4). The information you give in the questionnaire and your bowel diary will determine if you are eligible to continue to Part 1.

2. **Part 1.** In Part 1, women will be randomly assigned (like flipping a coin or drawing straws) to get either PTNS or sham stimulation. This means that 2 women will get PTNS for every 1 woman that gets the sham treatment (or placebo). Each treatment (PTNS or sham) will be given to you for 30 minutes each week for 12 weeks. In other words, you will get a total of 12 treatments during Part 1. You will also be asked to fill out a 14-day bowel diary using the phone app at 3 time points. The information you give in the questionnaire and your bowel diary will determine if you can move on to Part 2.

3. **Part 2.** If your accidental bowel leakage has gotten better at the end of Part 1, you will go on to Part 2. During Part 2 of the study, women will be randomly assigned (like flipping a coin or drawing straws) to one of two plans that will last 9 months. During the 9-months, you will also be asked to fill out a 14-day bowel diary using the phone app at 3 time points.

   More information about the three parts is explained below.

A. Run-In Phase

VISIT 1: Screening Visit: This visit will take about 90 minutes.

- Study staff will explain the study and you will be asked to read and sign this consent form.
- Study staff will ask you about any treatments that you have had for your accidental bowel leakage.
- A doctor or his/her trained assistant will do a rectal and pelvic (vaginal) exam. During the exam, you will be asked to push down a few times. This helps us determine if you have vaginal or rectal prolapse. Vaginal prolapse is when the top of the vaginal wall and the pelvic organs behind it bulge through the opening of the vagina. With rectal prolapse, the walls of the rectum come out through the anus. This exam will take about 2 minutes. If this exam has been recently done by a PFDN investigator, it will not be repeated.
- Study staff will give you information about causes and treatments for accidental bowel leakage, also called fecal incontinence.
- You will be asked to complete questionnaires about your medical and surgical history, the severity of your accidental bowel leakage, and how it has impacted the quality of your life. Completing these forms will take about 5 minutes.
- If you are currently taking medication or fiber supplements for accidental bowel leakage, please do not increase the amount or how often you use the medication throughout the study. You may choose to take less or stop the treatment if you do not need it anymore.
- While you are in the study, we ask that you do not start any other treatments for your accidental bowel leakage.

Week 1 and Week 4:

- If you are eligible to participate in the 4-week Run-In Phase, you will be asked to fill out a bowel diary during the first and the fourth week. It will take one or two minutes each day to fill in the diary. In this diary, you will record each time that you have a bowel movement, if you have an urge to move your bowels, and when you leak stool. If you own a smartphone, we will ask for your permission to download an app which will allow you to do the bowel diary on your smartphone. If you do not have a smartphone, study staff will tell you how to do your bowel diary in a paper booklet. Please bring your completed paper bowel diaries or your smartphone to your study visits after Week 4. The study staff will assess your bowel diary and questionnaire to determine if you can move on to Part 1 of the study. Some women's leakage symptoms will improve at the end of the Run-In Phase and there will be no need for those women to continue in the study. If your leakage symptoms have not improved, you will start Part 1.

B. Part 1: Treatment Phase

VISIT 2: Baseline: This visit will take about 90 minutes.

You will return to the office and study staff will review your diary and questionnaire to see if you are eligible to continue in the study. If you are not eligible to continue, you will be finished with the study. If you are eligible to continue with the study, you will be asked to complete more questionnaires about your accidental bowel leakage and how it affects your life. These forms will take about 45 minutes to complete. Study staff will also perform a urine pregnancy test if you can become pregnant.

You will be asked to complete a 14-day bowel diary at home on a smartphone. If you do not own a smartphone, one will be loaned to you for use during the study so that you can complete the diary. You will

be given instructions on how to enter information into the Bowel Diary phone app. **You should bring your smartphone to each visit**. Recording daily bowel events in your smartphone should take less than a minute or two. If you are loaned a phone for use during the study, you will not be able to use the phone to make international calls or those to Hawaii and Alaska. You will, however, have the ability to text and make calls within the mainland of the United States.

VISIT 3: Randomization and First Treatment: This visit will take about one hour.

You will return to the office two weeks after your baseline visit for the First Treatment of Part 1. You will be asked if there has been a change in your health since your last visit. You then will be randomly assigned (like flipping a coin or drawing straws) to get either PTNS treatment or sham (placebo) treatment. You will not know which treatment you are getting until the study ends. Two women will be selected for PTNS for every 1 woman selected for sham. Neither you nor your doctor will decide which treatment you will receive. Your first treatment will be at this visit.

Note that you will be assigned to a group by chance, and this group may prove to be less effective or to have more side effects than the other study group or alternatives.

During the PTNS treatment, you will lie on an exam table or recline in a chair and a trained practitioner will place a thin needle into your skin above your ankle and attach it to a nerve stimulator. The stimulator is a battery-powered machine which sends mild electrical pulses to the tibial nerve. Three surface electrodes (similar to small round Band-Aids) will also be placed on your foot and ankle. The stimulator will be turned on and adjusted so that you feel tingling in your foot. This tingling should not be uncomfortable. Stimulation will last for 30 minutes. After 30 minutes, the stimulator will be turned off, and the needle and three surface electrodes will be removed.

The sham (placebo) treatment will be done in the same way described above, but the tibial nerve will not be stimulated. After your treatment, you will be able go home and resume all normal activities.

The stimulation sessions will be done under the direct supervision of a member of the research team. If you have any symptoms that are concerning to you, please let the research team member know so that the symptoms can be assessed.

VISITS 4 THROUGH 14: Each visit will take about one hour.

All women in the study will be asked to return to the office every week for 11 additional stimulation treatments (a total of 12 stimulation treatments over a 3-month time period). You will be asked if there has been a change in your health since your last visit. At visits 7 and 11, you will be asked to complete questionnaires about how bowel leakage affects your quality of life, about your bladder and bowel function, and about the things that you do to make your accidental bowel leakage less bothersome (adaptive behaviors). The 30 minute PTNS or sham stimulation will occur at each visit. Additionally, you will be asked to complete the 14-day Bowel Diary using the phone app after Visit 8 (6th stimulation session) and after Visit 14 (final stimulation session). **You should bring your smartphone to each visit.**

VISIT 15: End of Part 1 and Beginning of Part 2: This visit will take about one hour.

You will return to the office 2 weeks after your last treatment visit. You will be asked to complete questionnaires about how bowel leakage affects your quality of life, about your bladder and bowel function, and about the things that you do to make your accidental bowel leakage less bothersome (adaptive behaviors). Study staff will review your 14-day bowel diary. If your questionnaires show enough improvement in your bowel leakage (which the investigators who designed this trial determined before starting the study), you will move on to Part 2. In Part 2 of the study, you will continue to receive your assigned treatment (PTNS or sham) on a new, less frequent schedule. If your bowel symptoms did not improve enough after 12 treatments, you will not move on to Part 2.

C. Part 2: Maintenance Phase

In Part 2 of the study, we are looking at how often the PTNS treatment needs to be repeated to continue the improvement in symptoms that you reported in Part 1. All women who continue into this phase of the study will receive their assigned treatment (PTNS or sham) for up to one year. This means that if you were receiving the "sham" stimulation and reported symptom improvement, you will continue that same treatment.

VISIT 15: Randomization and First Treatment of Part 2:

If you continue in Part 2 of the study, you will be randomly assigned (like flipping a coin or drawing straws) to one of 2 groups. One group will be assigned to a Fixed Schedule of Treatment Visits, and the other group will be assigned to a "PRN" (As Needed) Schedule of Treatment Visits. Those assigned to the "Fixed Schedule" will get a treatment on this day. The treatment will be in addition to completing the study tasks as described in Visit 15 under Part 1 above. In other words, you will complete study tasks to end Part 1 and begin Part 2 on the same visit, Visit 15.

Fixed Schedule of Treatments: Each visit will take about one hour.

Women in the Fixed Schedule of Treatments group will have their PTNS or sham treatment done at this visit, Visit 15, and then come back to the office 11 more times over the next 9 months for regularly scheduled treatments. Each visit will be the same as the treatment visits in Part 1 of the study. The stimulation session will last 30 minutes. Study staff will ask you to complete questionnaires 3 times during Part 2 (Visits 19, 22, and 26) and will update your medical history. You will be asked to complete a 14-day bowel diary using the phone app 3 times during Part 2 (Visits 19, 22, and 25). The Fixed Schedule of study visits is as follows:

Visit 16	Two weeks after Visit 15
Visit 17	Three weeks after Visit 16
Visit 18	Three weeks after Visit 17
Visits 19-25	Four weeks after Visit 18 and every 4 weeks until 1 year after you started the study.

PRN (As Needed) Schedule of Treatments: Each visit will take about one hour.

Women in the PRN "As Needed" Schedule of Treatments group who report that they are not satisfied with the control of their bowel symptoms will be offered a treatment during Visit 15. In future weeks, they will be contacted by telephone at the same intervals described above (for visits 16-25) and will be asked how satisfied they are with their control of bowel symptoms. If you report that you are not satisfied with the control of your bowel symptoms, you will be scheduled to come in for a treatment. The number and timing of your treatments will depend upon whether you are satisfied with control of your bowel symptoms. If you are experiencing symptoms between the scheduled phone contact and would like to have a treatment sooner, you can call the study coordinator. The staff will assess your symptoms and will schedule you for a treatment within 3 working days.

The treatment visits take about 1 hour and will be like all prior stimulation sessions in Part 1. You will be asked to complete a 14-day bowel diary using the phone app. 3 times during Part 2 (Visits 19, 22, and 25). Study staff will ask you to complete questionnaires 3 times during Part 2 (Visits 19, 22, and 26) and will update your medical history. The questionnaires can be completed in person if you are coming in for a visit, or they will be mailed to you with a self-addressed stamped envelope to complete at home and to return to the study office. A third option is to complete the questionnaires via the web if you have internet access at home.

VISIT 26: Final Study Visit: This visit will take about one hour.

The Final Study Visit for both groups in Part 2 will occur 1 year after your first treatment session. It will be 2 weeks after the last treatment. All women who participate in Part 2 of the study will complete this visit. Two weeks before this visit, we will ask that you complete the 14-day Bowel Diary phone app and bring your phone with you to this visit. We will review this final bowel diary at this visit and collect all smartphones that we provided. You will be asked to complete questionnaires about how bowel leakage affects your quality of life, about your bladder and bowel function, and about the things that you do to make your accidental bowel leakage less bothersome (adaptive behaviors). You will not get a treatment at this visit.

Additional Information Related to Your Participation:

After 147 women have completed Part 1 of the study, the research team will look at the results of the two types of stimulation. If PTNS is found to be better than sham (placebo) stimulation in reducing bowel leakage, the sham treatment will be discontinued. Any woman assigned to the sham group who continues to report bowel leakage symptoms and meets the study criteria, will be invited to "start over" in the PTNS group. She will go through 12 weekly PTNS sessions in Part 1, and if her bowel leakage symptoms improve she will be randomly assigned to either the Fixed or "PRN" schedule of PTNS treatments in Part 2.

A woman whose bowel leakage symptoms improve after sham treatment may be doing well enough that she will no longer meet study criteria and will not be eligible to "start over" in the PTNS group. Her participation in the study will end. Additionally, the study will no longer provide sham stimulation.

If Part 1 of the study shows that PTNS is not better than sham, the study will end for all participants even if

their bowel leakage symptoms improved with PTNS or sham. All participants will be informed about which treatment they received. Women can be treated outside of the study by their doctor(s) after they are finished with the study. Other treatments may include constipating medications, pelvic muscle strengthening exercises, dietary changes, sacral nerve neuromodulation, and anal sphincter surgery. Your doctor can tell you more about these treatments. Medical insurance companies do not pay for PTNS treatment for accidental bowel leakage.

What are the possible risks, side effects, and discomforts of this research study?

Questionnaires and Completing the Bowel Diary: These materials contain items that are personal and may make you uncomfortable or embarrassed. For example, some questions will ask about your sexual activity. You may refuse to answer any question that you do not want to answer.

Pelvic and Rectal Exam: You may experience some mild discomfort with this exam. It is like a pap smear or other general gynecologic evaluation. Experienced examiners will be performing the exam to decrease your discomfort.

PTNS: No serious adverse events or complications have been reported in any of the studies of PTNS for either urinary symptoms or accidental bowel leakage. Frequently reported "side effects", occurring in 10% or more of women (1 or more out of 10), include slight bleeding at the needle insertion site. Uncommon "side effects", occurring in less than 1% of women (or about 1 out of 100), include swelling of the foot or bruising at the site of needle insertion, worsening of incontinence, headache, blood in the urine, inability to tolerate stimulation, leg cramps, fainting in response to needle placement, a temporary painful, numb or tingling feeling at the needle placement site, the sole of the foot or the toes on the foot receiving stimulation. Additional risks include skin irritation and burns beneath the electrodes. If you have broken skin or an infection around the ankle where the electrode and needle would be placed, you will not receive PTNS treatment.

Sham Treatment: Infrequent side effects include skin irritation, bruising, bleeding, temporary burning, itching or pain around the needle or beneath the surface electrode placement site, and altered sensation in the toe of the foot receiving stimulation. If you have broken skin or an infection around the ankle where the electrode and needle would be placed, you will not receive sham treatment.

Pulse Generator/Electrical Stimulator: There are no published reports of cardiac (heart) related side effects. Please tell the study team if you have been diagnosed with a cardiac rhythm abnormality. If you have a pacemaker or implanted defibrillator, you cannot take part in this study. The stimulation sessions will be done under the direct supervision of a member of the research team. If you have any symptoms that are concerning to you, please let the research team member know so that the symptoms can be assessed by a trained staff member.

Risks to Embryo or Fetus: If you are part of this study while pregnant, it is possible that you may expose the unborn child to risks. For that reason, pregnant females cannot participate in the study. If you can become pregnant, a urine pregnancy test will be done and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes:

1) surgical sterilization (such as hysterectomy or "tubes tied"),
2) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon),
3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
4) an intrauterine device (IUD).

If you do become pregnant during this study, you must tell the researchers immediately.

Downloading and Using the Bowel Diary Phone App on Your Personal Smartphone:
The use of technology as part of this research study can present minimal risks. It is possible that the information you enter into the bowel diary app could be seen by others if you lose your mobile phone or lend it to other people. You can make this risk smaller if you have a password on your smartphone. It is also recommended that a remote disable feature be set up on your smartphone in case it is lost or stolen. This will allow you to remotely disable or remove any apps and/or data.
If you enter your bowel information into the bowel diary app while in a public place, there is the risk that someone could see this information and you could feel a loss of privacy or confidentiality. Unlike other apps, this bowel diary app does not collect other information about you such as your location, browser history, or contact information.

Data Transmission and Storage on Electronic Devices: Research data will be sent from the bowel diary app to the research team. It will be labeled with your study assigned identification number (ID) not your name or your phone number. We will keep this information confidential by limiting who can see the research data and by storing research data in secure password-protected computers. We will take great care to protect your information; however, there is a slight risk of loss of confidentiality. This is a low risk because the research team will separate your personal information (information that can directly identify you, such as your name or phone number) from the research data and identify you only by a study assigned identification number (ID).

What are the possible benefits of this research study?
There may be no benefit to you during your participation in this research study. You may see improvement in your bowel symptoms during your participation, but this is not guaranteed.

What treatments or procedures are available if I decide not to take part in this research study?
You do not have to participate in this study to get health care with your doctor or at this medical institution. Other treatments may include constipating medications, pelvic muscle strengthening exercises, dietary changes, sacral nerve neuromodulation, and anal sphincter surgery. Your doctor can provide more information about these alternative treatments. PTNS is currently not a covered treatment for accidental bowel leakage by insurance companies.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be quickly notified if, during the course of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you nor your insurance company will be charged for any of the visits explained in this consent form. All costs related to PTNS and sham treatments will be paid for by the study. Any additional treatments or visits to your doctor for care outside of these described visits will be charged to you or your insurance company in the usual manner. You will be responsible for any copays, deductibles, or coinsurances related to these additional visits.

Will I be paid if I take part in this research study?

We recognize that participation in this study will take up your time to complete the questionnaires and the bowel diary, and to travel to and attend the treatment sessions. You will be given a research participation fee to partly cover your time, effort, and travel expenses related to completing your study responsibilities (including transportation, parking, missed work, etc.).

Visit	Study Assessment	Participant Payment
Visit 1	**Run-In Phase**	$25
Visit 2	**Run-In:** $25 visit; $50 for completed Run-In diary **Part 1**: $25 questionnaires	$75 $25
Visit 3	**Part 1**: $50 treatment; $50 for completed Baseline diary	$100
Visit 4	**Part 1**: $50 treatment	$50
Visit 5	**Part 1:** $50 treatment	$50
Visit 6	**Part 1:** $50 treatment	$50
Visit 7	**Part 1:** $50 treatment	$50
Visit 8	**Part 1:** $50 treatment	$50
Visit 9	**Part 1:** $50 treatment	$50
Visit 10	**Part 1:** $50 treatment; $50 for completed diary which starts after Visit 8	$100
Visit 11	**Part 1:** $50 treatment	$50
Visit 12	**Part 1:** $50 treatment	$50
Visit 13	**Part 1:** $50 treatment	$50
Visit 14	**Part 1:** $50 treatment	$50
Visit 15	**Part 1:** $50 diary completion which starts after Visit 14; $50 for completing questionnaire for end of Part 1	$100
TOTAL RUN-IN + PART 1		**$925**
Visit 19	**Part 2:** $50 questionnaires	$50
Visit 20	$50 diary completion which starts after Visit 19	$50
Visit 22	**Part 2:** $50 questionnaires	$50
Visit 23	$50 diary completion which starts after Visit 22	$50
Visit 26	**Part 2:** $100 questionnaires; $50 diary completion which starts after Visit 25	$150

Visit	Study Assessment	Participant Payment
TOTAL ENTIRE STUDY		**$1,275**

If you complete Visit 1 but are found to be ineligible at Visit 2, you will receive $100 ($25 for each visit you attend and $50 for completing the bowel diary).

If you complete all 14 visits in Part 1, you will receive $925.

- $25 at the screening visit (Visit 1).
- $50 at the baseline visit (Visit 2), plus $50 for completing the bowel diary prior to this visit.
- $50 at visits 3 through 15, plus $50 for completing the diary 2 weeks prior to Visit 3 and after treatment 6 and treatment 12.

If you complete Part 2, you will receive an additional $350.

- Part 2: $100 at 6 months and 9 months for completion of questionnaires ($50) and diary ($50) regardless of schedule assignment (for a total of $200).
- Part 2: $150 at the final visit for completion of questionnaires ($100) and diary ($50).

If you are eligible and chose to participate in the year-long study of Part 1 and Part 2, you may be paid up to a total of $1275. Payment will be made in the form of a debit card and the reimbursement amounts will be added after completion of each visit.

If you are eligible to "start over" in the PTNS group and repeat Part 1 of the study a second time because you were originally assigned to the sham stimulation group, you will be eligible to receive participant payment for each visit you complete. If you then proceed to Part 2, you will also be eligible to receive participant payment for each visit you complete.

You are responsible for paying any state, federal, Social Security, or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Who will pay if I am injured as a result of taking part in this study?

University of Pennsylvania researchers and their associates who provide services at the University of Pennsylvania Hospitals recognize the importance of your voluntary participation in their research studies. We will offer you the care needed to treat injuries directly resulting from taking part in this research.We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part ink this research study, tell the person in charge of the research study as soon as possible . The researcher's name and phone number are listed on the first page of this consent form..

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Will this research study involve the use or disclosure of my identifiable medical information?
This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office) records. The information that will be recorded will be limited to information concerning your evaluation and treatment for accidental bowel leakage.

This research study will result in identifiable information that will be placed into your medical records held at University of Pennsylvania Hospitals. A copy of your signed informed consent form will be placed in your chart. Study notes at study visits will also be placed in your medical record. The information gathered from the Bowel Diary phone app will not be stored in your medical record. Your primary care physician and other

providers will not be able to view the information you shared in this diary during your participation in the study. If you have never received care within this health system (outpatient or inpatient) and are participating in this research study, a medical record will be created for you to maintain results of research tests or procedures.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Pelvic Floor Disorders Network (PFDN) plans to make data generated by PFDN studies available to external researchers in accordance with NIH data sharing policies. Data to be shared include clinical datasets of variables collected via the electronic data capture system, and analysis datasets containing derived variables that would enable a researcher to reproduce published study results. The data will be de-identified to protect study participant confidentiality. PFDN Data Coordinating Center (DCC) statisticians will implement a series of steps to de-identify study datasets in order to minimize the risk of researchers identifying any individuals in the data. This process will be consistent with Health Insurance Portability and Accountability Act (HIPAA), Health and Human Services (HHS) policies for protection of human research subjects, and related requirements for protecting participant confidentiality. The PFDN Steering Committee will have the opportunity to review and approve each request for the Network's data prior to release of the data.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pennsylvania Institutional Review Board and Office of Regulatory Affairs may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

Authorized representatives of the sponsor (NICHD) and the Data Coordinating Center of this research study will review and/or obtain identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical information, the University of Pennsylvania cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical information related to your participation in the study.

Authorized representatives of the University of Pennsylvania hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

Authorized representatives of the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration may review and/or obtain your identifiable medical record information for the purpose of monitoring the accuracy of the research data. While the U.S. Food and Drug Administration understands the importance of maintaining the confidentiality of your identifiable medical record information, the University of Pennsylvania cannot guarantee the confidentiality of this information after it has been obtained by the U.S. Food and Drug Administration.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

May I have access to my medical information that results from my participation in this research study?

,You are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider after your study participation or if needed for medical care.

What additional confidentiality (privacy) protections are provided by a federal Confidentiality Certificate?

To further help to protect your privacy, the investigators have obtained a Confidentiality Certificate from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. With this federal Certificate, the investigators cannot be forced (for example, by court order) to disclose information that may identify you in any federal, state or local court; administrative; legislative; or other proceeding. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, an as explained below.

You should understand that this federal Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research study. Note, however, that if an insurer or employer learns about your study participation and obtains your consent to receive your identifiable information, then the investigators may not use the Certificate to withhold this information from the insurer or employer. This means that you or your family must also actively protect your privacy. Finally, you should also understand that this federal Certificate does not prevent investigators from taking steps, including reporting to appropriate authorities, to prevent serious harm to yourself or others.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pennsylvania. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a University of Pennsylvania hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pennsylvania. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a University of Pennsylvania hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers if, for example, your study doctor determines that it is no longer in your best interests to continue. If you are removed from the study, medical record information regarding complications may continue to be collected. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include unexpected adverse events or new information regarding the safety or effectiveness of PTNS. If this occurs, you will be notified and your study doctor will discuss other options with you.

Whom do I call if I have questions or problems?
For questions about the study, contact [Dr. Lily Arya] at [PI's number with area code] during regular business hours and at [215-662-6035] after hours and on weekends and holidays.

CONTACT FOR FUTURE RESEARCH

There may be studies in the future that may be of interest to you. May we have your permission to contact you in the future to discuss other research projects? The person contacting you would be your physician or a member of this research team. Please initial below to indicate your permission regarding contact for future research.

_____ Yes, you may contact me in the future regarding research projects.

_____ No, you may not contact me in the future regarding research projects.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Office of Regulatory Affairs at the University of Pennsylvania (215-898-2614) to discuss my rights as a research participant, problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____	_____	_____	_____
Participant Signature	**Printed Name of Participant**	**Date**	**Time**

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____	
Printed Name of Person Obtaining Consent	Role in Research Study	
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time