Previously Implanted Pudendal Nerve Stimulation

NCT04473469

Date of IRB Approval: March 5, 2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Previously Implanted Pudendal Nerve Stimulation Study

Company or agency sponsoring the study: National Institutes of Health and [redacted]

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Tim Bruns, Ph.D., Department of Biomedical Engineering, University of Michigan
Co-Principal Investigator: Priyanka Gupta, M.D., Department of Urology, University of Michigan
Study Coordinator: Mackenzie Moore, M.P.H., Department of Biomedical Engineering, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research seeks to learn more about the pudendal nerve by studying patients who were previously implanted with a neurostimulator for pelvic pain, bladder problems, and/or other medical conditions. As part of this study you will undergo a standard clinical cystometrogram, to study your bladder's function. Additionally, we will collect information in the form of surveys about your bladder, bowel, and sexual function, pelvic pain, and some demographical information at the start of the study. You will also complete brief pelvic function diaries in the days before and after the study day.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include a loss of privacy, infection, and pain. More detailed information will be provided later in this document.

The researchers do not expect that this study will provide any benefit for your current conditions. This study may benefit others in the future by giving researchers more knowledge about how the pudendal nerve helps control the bladder system, which may help future patients who receive a neurostimulator at the pudendal nerve. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about three hours during a one-month time period, across the research visit, pre-visit surveys, and pelvic diaries.

You can decide not to be in this study. You will still receive your normal clinical care regardless of your participation in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The goal of this study is to examine the response of the bladder and urethra to different pudendal nerve stimulation patterns in patients previously implanted with a pudendal nerve neurostimulator. The pudendal nerve goes to the urethra, anus, and other areas of the pelvic floor. Electrical stimulation of this nerve can help with bladder, bowel, and sexual problems, and pelvic pain. Researchers do not fully understand how the nerve helps with these functions or how the anatomy is different between people. Researchers in this study will stimulate your nerve while recording from the bladder and pelvic floor to understand how the nerve connects to the different parts of the body and how different stimulation patterns may cause different pelvic responses. A greater understanding of how the pudendal nerve can be controlled with stimulation may help improve the medical care for future patients with bladder problems, pelvic pain, bowel problems, and/or sexual problems.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may be able to take part in this study if:

- You are at least 18 years' old
- You have previously received an implanted neurostimulator at the pudendal nerve.
- You can speak, read, and understand English.
- You are capable and willing to follow study procedures.

You CANNOT take part in this study if:

- You are pregnant or planning to become pregnant during the period of this study.
- You currently have a urinary tract infection (UTI).
- You are unable or unwilling to undergo any of the study tests.
- You currently have or tested positive for COVID-19 in the last 14 days or are symptomatic for COVID-19.
- You do not agree to allow the researchers to store your study data for future research (see below).

3.2 How many people are expected to take part in this study?

We expect to enroll 10 subjects in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you meet eligibility criteria, you will be asked if you would like to enroll in the study. If you enroll in the study, you will complete several surveys and then about five days later you will have one study visit; at which time the consent form will be signed. Additionally, you will be asked to complete a pelvic function diary two days before, the day of, and two days after the study visit.

Surveys and Diaries

At the start of the study, you will be asked to take surveys on your bladder function, bowel function, sexual function, pelvic pain, and demographics. These surveys will be completed by phone, online, or on paper by mail, and will take approximately thirty minutes to complete.

You will also be asked to complete short pelvic function diaries for five days around the study visit (for two days before, the day of, and for two days after).

Study Visit: Test Session

In the one study visit you will have a test called a cystometrogram. The study coordinator will provide information on the test location, which will occur at the University of Michigan Health System in Ann Arbor or a nearby University of Michigan Health System location. At this visit, pre-menopausal women who are capable of becoming pregnant will complete a urine pregnancy test. We will fill your bladder with saline. We will put sticker sensors on your pelvis and catheters in your urethra and rectum or vagina. We will stimulate your nerve by setting your implanted stimulator to different settings. During the test, we may ask you to cough, forcefully exhale, or perform a similar maneuver. At the end of the cystometrogram test your implanted stimulator will be returned to its normal settings. The total time for the cystometrogram will be about two hours, including preparation for the test.

Unspecified Future Research

Besides the information about the main study, the following information is specific to unspecified future use of study data. We would like your permission to keep your study data, which includes your relevant medical information, survey and diary responses, and sensor signals taken during the cystometrogram test so that we may study them in future research. The future research may be similar to this study or may be completely different.

You can only take part in this study if you decide to let us keep your study data for future research. Even if you give us permission now to keep your medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your study data we may not be able to take the information out of our research.

We may share your study data with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your study data with other researchers, we will not be able to get it back.

The only possible risk the future research may pose is a loss of privacy. Upon the completion of this study, all patient-identifying information will be deleted and there will not be a way to connect your study data with you. Future use of your study data will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your study data. Allowing us to do future research on your study data will not benefit you directly.

With appropriate permissions, your study data may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
Your total time commitment is up to 3 hours over approximately 1 month, including a clinic visit and surveys and diaries that are completed at home.

4.3 When will my participation in the study be over?
Your participation in the study will be over after you have completed the study visit and completed the final daily diaries.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information, surveys, and study results may be shared with the National Institutes of Health and other researchers seeking to understand the pudendal nerve and bladder function.

With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens will be stripped of identifiers and may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risks related to the clinical catheters:

The standard urethra and rectal catheters used during the cystometrogram testing have a risk of temporary infection (e.g. urinary tract infection), blood in the urine, temporary irritable voiding, accidental injury to involved areas and surroundings structures like urethra or anus. Anything placed into your body has a risk of infection, even in the case of temporary use like these catheters. The likelihood of this risk is very low. These catheters are often used in normal clinical care. The clinical staff will sterilize all sensors before use and will take all necessary precautions to reduce the risk of urinary tract infections or other infections due to their use. It is also standard clinical practice for patients to be offered an antibiotic medication right before testing begins to also reduce the risk of infection.

Risks related to electrical stimulation:

During cystometrogram, the electrical current from the implanted stimulator may be tested over a range of amplitudes. Side effects related to higher currents, such as muscle contractions, may occur, but are known to be reversible by either reducing the amplitude of the stimulation or stopping the stimulation entirely. Whenever using electricity to stimulate tissue, there is also the possibility of a shock hazard, including an electrical burn. However, only electrical stimulators approved by the United States Food and Drug Administration will be used in this study. Therefore, the risk of tissue damage or electrical shock during the electrical stimulation is minimal.

Each of these risks is expected to be rare or uncommon (1-10% of patients). There are no known risks to a fetus, should you become pregnant after study participation.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

The clinical staff will sterilize all sensors before use and will take all necessary precautions to reduce the risk of urinary tract infections or other infections due to their use. The neurostimulator parameters can be returned to normal settings or off if pain or shock due to stimulation occurs.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Through this study we will gain new knowledge about how the pudendal nerve functions. Researchers may use the knowledge gained in this study to improve or develop treatments for bladder problems, bowel problems, sexual problems, and/or pelvic pain.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation in this study is entirely *voluntary*. The alternative option is not to participate in the study. Your clinical care will not be affected by your decision to participate or not participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no harm that may come to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.

- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive $50 for completing all parts of the study, including the surveys, diaries, and study visit.

8.3 Who could profit or financially benefit from the study results?

No person or organization involved in the conduct of this study has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

[redacted] They are not likely to benefit financially from the results of the study. No researchers involved in this study receive payment per participant, incentive payments, or compensation that is affected by the study outcome.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?
Every effort will be made to maintain your privacy. You will be given a unique study identification number. This number will be used to record your study information. You will never be tracked through the study by name, medical record number, or other personal identifier.

Research records are stored in a secure, locked location and will not be made a part of your regular medical record. Data will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Identifiable data (such as the screening and consent forms) are stored separately. Only authorized members of the research study will have permission to see these data. If the researchers order any tests, the order and results may become part of your regular medical record.

If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Tim Bruns, Ph.D.
Mailing Address:
Biointerfaces Bruns Group
2800 Plymouth Road. NCRC B10-A169
Ann Arbor, MI 48109
Telephone: 734-647-8727

Co-Principal Investigator: Priyanka Gupta, M.D.
Mailing Address:
Taubman Center, Floor 2 Reception C
1500 E Medical Center Dr, SPC 5330
Ann Arbor, MI 48109
Telephone: 734-836-7030

Study Coordinator: Mackenzie Moore, M.P.H.
Mailing Address:
Biointerfaces Bruns Group
2800 Plymouth Road. NCRC B14-186
Ann Arbor, MI 48109
Telephone: 734-647-8568

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____