Pudendal Nerve Mapping Towards Improved Neuromodulation for Urinary Retention

NCT04236596

Date of IRB Approval: September 24, 2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Pudendal nerve mapping towards improved neuromodulation for urinary retention

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

Names, degrees, and affiliations of the principal investigator and study coordinator:
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.

You will be receiving an implanted stimulator for your bladder or pelvic problems as part of your clinical care. We want to understand the anatomy of the pudendal nerve, the main nerve found in the pelvis that carries sensation from the urethra, anus, and external genitalia of both sexes and how electrical stimulation from the implanted stimulator can affect it. As a part of this study you will have MRI and CT scans performed, so that we can look at the nerve and the implant. Sensors were placed during the surgery as part of your normal standard of care. We will record data from those sensors to understand how the stimulator activates the nerve. We will use MRI images, CT images and the sensor information to make a computer model of how the implant stimulates your pudendal nerve. Finally, after receiving the stimulator and after your normal clinical visits we will study how the pudendal nerve controls your bladder. For this, you will undergo a test to study your bladder function, called a cystometrogram. Also, as part of this study, we will collect information about your bladder, bowel, and sexual function, pelvic pain, and some demographical information.

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, claustrophobia, and an

exposure to radiation during imaging procedures. More detailed information will be provided later in this document.

The researchers do not expect that this study will offer any benefit to you now. Others in the future may benefit if this study helps better understand how pudendal nerve stimulation can improve pelvic organ function and pelvic pain. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be up to seven hours during a time period of about three months across your clinical care visits for your implanted stimulator, including a clinic visit for an MRI, a clinic visit for a CT scan after your stage-2 implant, and a bladder test after your 2-month clinic follow-up visit.

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 map the pudendal nerve. This nerve goes to the urethra, anus, and other areas of the pelvic floor. Electrical stimulation of this nerve can help with bladder problems and pelvic pain. Researchers do not understand how the nerve anatomy is different between people. Successfully mapping the pudendal nerve may help improve the medical care for future patients with bladder problems, pelvic pain, bowel problems, and sexual problems. In this study we will examine subjects who are already receiving an implanted stimulator at their pudendal nerve as part of their normal clinical care.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you do not 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 will be receiving an implanted stimulator at your pudendal nerve as part of your clinical care.
- 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 have any materials in your body that prevent you from undergoing MRI. Potential contraindications to MRI include cardiac pacemakers, neurostimulators (e.g. deep brain stimulator, vagal nerve stimulator), intracranial metal clips (e.g. aneurysm clips), implanted hearing aids (e.g. cochlear), eye lens implant, metallic foreign bodies in the eye, artificial limb or prostheses, insulin pumps, and certain metallic dental materials, metal hip replacements, surgical clips/stables, wires/plates/screws/cages, and sutures or foreign bodies in other sites. You will be asked these questions as part of the screening process, in such cases, the radiologist will make the final decision whether or not you can proceed with the MRI examination.

- You have any medical problems that prevent you from lying flat during an MRI or you are claustrophobic.
- You have a bladder that does not work at all, such as an atonic bladder.
- You are pregnant or planning to become pregnant during the period of this study.
- You are unable or unwilling to undergo any of the study tests.
- You have any problems with the nerves that are involved with bladder function.
- 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 40 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 have four study visits that will overlap with your normal clinical care visits and you will complete surveys.

Study Visits
The study visits will occur over a three-month time span and will be at the University of Michigan Health System in Ann Arbor or another nearby University of Michigan Health System location. At each visit, pre-menopausal subjects will complete a urine pregnancy test.

Visit 1: MRI
Up to one month prior to the stage-1 surgery for your pudendal nerve stimulator you will have a magnetic resonance imaging (MRI). This MRI session is the only research study visit that is not planned to happen during a normal clinic visit. If you are entering this study with a neurostimulator that is not MRI compatible but is being removed as part of your clinical care, the MRI session will be after your stage-1 surgery and may occur during a clinic visit. Prior to undergoing the MRI scan, we will have you complete an MRI Safety Screen to ensure it is safe for you to undergo an MRI. If you are a woman and able to become pregnant, we will ask you to provide us with a urine sample so that we can confirm that you are not pregnant. Directions to the MRI suite will be provided by the study coordinator prior to your visit. An MRI machine uses magnets to create images of the inside of the body. MRI does not expose you to radiation. During this session we will use the MRI to look at pudendal nerve on each side of your body, as it goes from your spinal cord in your lower back to the bottom of your pelvis, also known as your pelvic floor. These images will be taken while you are laying on your back.

The total time for this MRI less than 2 hours, including preparation.

Visit 2: Stage-1 implantation
Your second research visit will be your normally scheduled surgery for the stage-1 implantation of the neurostimulator lead. Your doctor and clinical team will prepare you for the surgery using the same steps whether you participate in this research or not. During the surgery, your clinical team will place sensors in your urethra and rectum to measure how the implanted stimulator excites the pudendal nerve. We will record the signals from these sensors. The placement of the sensors and recording stimulation signals with them may add up to 30 minutes to your surgery duration.

Visit 3: CT scan
About two weeks after your stage-1 surgery, you will undergo the stage-2 procedure to implant the neurostimulator device. This will occur if your doctor determines you have responded to the

neurostimulator lead. This stage-2 surgery is part of your normal healthcare and will occur regardless of your participation in this research. Either right before or just after your stage-2 surgery, you will have a computed tomography (CT) scan performed for this research study; this will occur during the same clinic visit as the state-2 surgery. The CT scan will take images of your spine and pelvis, and will show us the location of your neurostimulator lead. CT does expose you to some radiation (see section 5, below, for CT risks). Our research team will use the CT and MRI images to make a computer model of the neurostimulator and your nerves to understand how the implant may stimulate the nerve.
The total time for the CT scan will be less than 1 hour.

Visit 4: Cystometrogram testing

About 4-6 weeks after your stage-2 surgery you will have a clinic visit as part of your normal healthcare for your implant. After this visit you will have a test called a cystometrogram for this research. The study coordinator will provide information on the test location, which will be at the same location you have your clinic visit. During a cystometrogram, sensors will be placed in your urethra, bladder, and rectum or vagina, as well as on your abdomen and/or back. Warm saline will be used to fill the bladder through a catheter until full. We will test our ability to model your nerve by setting your implanted stimulator to different parameters while your bladder is filled or emptied. During the test, we may ask you to cough, forcefully exhale, or perform a similar maneuver. At the end of the cystometrogram your implanted stimulator will be returned to its normal settings. The total time for the cystometrogram will be about 2 hours, including preparation for the test.

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 online or over the phone and will take approximately 30 minutes to complete. Additionally, some participants who have urinary retention with detrusor underactivity will be asked to complete 3 additional surveys on their catheter use, quality of life and sexual health.

Bladder diaries that you complete as part of your normal clinical care will be studied by the research team.

Finally, near the time of the *Visit 4* cystometrogram test you will repeat the surveys on your bladder, bowel, pelvic pain, and sexual function. Some participants who have urinary retention with detrusor underactivity will also take these surveys at about 2 weeks and about 6 months after the stage-1 implant.

Unspecified Future Research

Besides the information about the main study, the following information is specific to unspecified future use of study data. We would also like your permission to keep your study data, which includes your survey responses, MRI and CT images, sensor signals taken during the visit 2 implant procedure, and sensor signals during the visit 4 cystometrogram, and medical information collected in the main study, 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 the main study if you decide to let us keep your study data for future research. Even if you give us permission now to keep some of 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 7 hours over approximately 3 months.

4.3 When will my participation in the study be over?
Your participation in the study is over after you have completed visit 4 and taken the final surveys.

4.4 What will happen with my information used in this study?
Your collected information, surveys and study results, nerve mapping, and the computer model of your nerve and implant 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 other researchers 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:

<u>Risks related to MRI</u>

We will obtain an MRI scan of part of your body before the device implantation. MRI scans are often performed on patients for diagnostic purposes. Also, to ensure additional safety for the MRI procedures, you will be asked to bring or wear clothing without metal fasteners and remove jewelry and any other metal objects from your body. We will also assess whether metallic objects that may be implanted (e.g. surgical clips or staples) are hazardous or acceptable.
If you report any sort of discomfort such as claustrophobia during the MRI procedure at any time, the researchers can stop the scan. You will also be able to talk to the MR technician throughout the procedure and will be able to let them know immediately if you want to stop the procedure and exit the scanner.

Risks related to X-ray CT:
You will have a CT scan that is not part of your usual medical treatment. CT scans are often performed on patients for diagnostic purposes. CT scan technology uses radiation. Excess radiation exposure can increase the risk of cancer. The amount of added radiation for this study is like being exposed to as much as 2 to 4 years' worth of everyday exposure from the sun and other environmental radiation (3 mSv per year). The risk of cancer due to this added exposure is very small compared to the natural risk of cancer.

Risks related to sensors:
The sensors used in the stage-1 surgery and stage-4 testing will be placed into your body, via your urethra and rectum. Anything placed into your body has a risk of infection, even in the case of temporary use like these sensors. The likelihood of this risk is very low. These sensors 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; this medication will be provided by and administered by the clinical staff. As part of your normal care for your implanted stimulator you will be on medications after the surgery, which will also help lower the risk of infection.

Risks related to electrical stimulation:
During the Visit 2 stage-1 implantation and the Visit 4 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**. If problems occur during any research visit, first aid will be provided, if needed.**

Imaging procedures (MRI and CT) performed as part of this study are for research purposes only. They are not meant to diagnose illnesses, find tumors, or detect any other defects. However, there is still a chance that this imaging could show a defect that is already in your body, such as a cyst or tumor. Many such defects are not important, but you may want to look into them further. Such a finding might require more studies, and maybe even medical treatment, neither of which would be paid for by the investigators, the sponsor, or the University of Michigan.

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, researchers will gain more knowledge about how the pudendal nerve is structured and functions. Researchers may use the knowledge gained in this study to improve 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. Unless you say otherwise, your information will be retained.
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 researchers' 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?
No. You will not be paid for taking part in this study.

For those who live far away from Ann Arbor, MI, or for who the cost of travel could result in financial hardship, there is an option to receive travel reimbursement. Eligibility for reimbursement would be at the discretion of the research team and only apply to research appointments that for some reason cannot be scheduled on the same day as a regular clinical care visit, which is always our first option for your convenience. Reimbursement amount will align with the Federal Travel Regulation mileage reimbursement rate.

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 the 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.

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.
- 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 the following document:

- 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): _____