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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 11/21/2022

Protocol Number: 2022P-000826

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
10/16/2023
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A Pilot Study to Assess Effects of Self-Administered Nitrous Oxide (SANO) on Urodynamic Study (UDS) Parameters
PRINCIPAL INVESTIGATOR: Heidi Rayala, MD/PhD
PROTOCOL NUMBER: 2022P-000826

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are scheduled to have a urodynamic study (UDS) soon.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- Your participation is completely voluntary.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- Your refusal to participate will not result in any consequences or any loss of benefits that you are otherwise entitled to receive.
- You can ask all the questions you want before you decide.
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Why is this research being done?
A urodynamic study (UDS) is a common procedure done to learn more about the cause of urinary symptoms. For some patients, UDS can be associated with anxiety or discomfort. Nitrous oxide (or laughing-gas) is a well-known sedative which is frequently used in dental offices and for pediatric procedures to reduce anxiety and pain. This study is being done to see if giving nitrous oxide at the time of UDS affects the measurements taken during the procedure, such as how much volume your bladder can hold, and pressures during urination.

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A PILOT STUDY TO ASSESS EFFECTS OF SELF-ADMINISTERED NITROUS OXIDE (SANO) ON URODYNAMIC STUDY (UDS) PARAMETERS
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If the measurements are the same with and without self-administered nitrous oxide (SANO), it could be suggested that nitrous oxide may be a useful way of reducing patient anxiety and pain during UDS. We use the term "SANO" to describe participants holding a mask to their face. The medical team will adjust the level of nitrous oxide based on your feedback during the UDS.

How long will the research last and what will I need to do?
It is expected that you will be in this research study for the length of your UDS and a 20-minute interview after the procedure. The total time will about 90 minutes. We will check your medical record for up to seven days after your UDS to make sure there were no problems after your procedure.

Your UDS procedure will consist of catheter placement and two "runs". Before the start of the procedure, a study staff member will help you put on a plastic gas mask. Nitrous oxide and oxygen will be given to you through this mask. This will be done by Dr. Heidi Rayala, a member of the research team. You will not do this yourself. The dose will be adjusted based on your comfort level but you won't be able to request more gas than allowed. You will receive nitrous oxide during catheter placement at the start of the UDS. During the two runs, you will either receive nitrous oxide (run 1) then oxygen (run 2), or oxygen (run 1) then nitrous oxide (run 2).

Before the day of your UDS, you will be asked questions related to your demographics and medical history to determine study eligibility and experience of the treatment. During your UDS, you will be asked to describe your anxiety and pain levels. Afterwards, you will be asked to complete a 15-20 minute structured interview with a study staff member to learn more about your experience during the UDS.

More detailed information about the study procedures can be found under ***"DESCRIPTION OF STUDY DETAILS".***

Is there any way being in this study could be harmful to me?
There are some potential side effects when using nitrous oxide. About 1 in 200 patients who are given nitrous oxide experience mild nausea and vomiting. Other people have reported facial redness, sweating, drowsiness or lightheadedness when using nitrous oxide.

More detailed information about the risks can be found under ***"RISKS AND DISCOMFORTS".***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include decreased anxiety and pain during your UDS procedure. The results of this research will improve scientific understanding of the impact of self-administered nitrous oxide on urodynamic measurements during UDS and other medical procedures.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate. If you choose not to participate, then you will undergo UDS without nitrous oxide. Currently, BIDMC does not offer any standard pain control measures during UDS to patients outside of this study.

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DETAILED INFORMATION SECTION

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by Dr. Heidi Rayala. There is no funding agency in this study. Neither BIDMC nor Dr. Heidi Rayala has/have any additional interests in this research project.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Heidi Rayala at [617] 667-3739.

PURPOSE

A UDS is a very common clinic procedure performed to assess bothersome urinary symptoms. As per usual routine for the UDS, each patient will have two catheters placed. Men will have one catheter placed in the penile urethra and one catheter in the rectum. Women will have one catheter placed in the urethra and one catheter in the vagina. Your bladder will be filled through one catheter until you have the urge to urinate. This method of filling and urinating is called a "run". At BIDMC, we standardly perform multiple runs during a UDS. The UDS is expected to last 30 minutes. The length of the procedure is expected to take about 2 minutes longer as you receive oxygen at the end. There will also be an additional 5 minutes to set up the nitrous oxide before the UDS begins.
Although generally well tolerated, patients may find it uncomfortable or anxiety-inducing due to the placement of ureteral and abdominal catheters. Nitrous oxide (laughing gas), is a safe drug used by dental and pediatric offices to reduce anxiety and pain. It is being adopted in many Urology clinics across the county for other office-based procedures.

This study is being done to understand whether nitrous oxide affects the outcomes being measured during a UDS, such as how much urine your bladder can hold, and pressures during urination. It is also important to see if patients' pain and anxiety levels during the UDS differ when receiving nitrous oxide. If it is found that nitrous oxide does not affect UDS measurements, then it may lead to improvements to pain and anxiety control for future patients undergoing the procedure.

The Nitrouseal ® system is used to deliver nitrous oxide and oxygen during this study. Nitrouseal ® is an FDA-cleared plastic gas mask that releases nitrous oxide in a safe, controlled manner while preventing the gas from leaking in the air. It is different from other similar devices as it can scavenge the exhaled waste gas. This prevents nitrous oxide from leaking out and affecting clinical staff. This is important because long-term exposure to nitrous oxide may have negative effects on health.

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STUDY PARTICIPANTS

You have been asked to be in the study because you are scheduled to have a clinically indicated urodynamic study.

Approximately 25 people will take part in this study at Beth Israel Deaconess Medical Center.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be in this research study for about one week.

After you sign the consent form, the following things will happen:

1. Screening Procedures: Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include the completion of a baseline questionnaire. This questionnaire will ask you information about your demographics, medical history and other information relevant to study procedures. Based on your answers, you may not be eligible for the study. In that scenario, your participation in the study will end and you will not need to do any other procedures as part of the study.

2. Randomization Procedures:

   It is not clear at this time which of the treatments in this study would have an effect on urodynamic measurements. For this reason, the treatment plan offered to you will be picked by chance [like the flip of a coin]. You will not be able to choose which treatment order you receive. The chances of receiving either of the treatment orders are approximately equal. After the randomization, you will be assigned to one of the following groups:

   Subjects will be randomized to either:
   - Group 1: First run with SANO, second run with Oxygen
   - Group 2: First run with Oxygen, second run with SANO

   Regardless of the group to which you are assigned, you will receive oxygen gas during one of the two UDS runs.

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3. Research Procedures: If you qualify to take part in this research study, you will undergo these research procedures:

Prior to UDS
On the day of your UDS, a member of the research team will ask you some questions about your anxiety and pain before the procedure. We expect the questionnaires to take approximately 3-5 minutes of your time.

During UDS
The UDS will consist of catheter placement and two "runs". Each run includes a "filling" phase and a "voiding" phase. At BIDMC, we standardly perform multiple runs during a UDS. The UDS is expected to last 30 minutes. The length of the procedure is expected to take about 2 minutes longer as you receive oxygen at the end. There will also be an additional 5 minutes to set up the nitrous oxide before the UDS begins.

During your UDS, you will hold the Nitrouseal® mask over your nose and chin. Please note you will be able to place and remove the mask as needed. You will be able to use hand signals to communicate while you have the mask on during the procedure. This will be important in helping the research team adjust the amount of gas you receive. A trained and qualified research staff member will monitor your condition and oxygen levels throughout the UDS to ensure your safety and well-being.

Nitrous oxide will be released through the mask while the UDS practitioner places a urethral and abdominal catheter at the beginning of the procedure. You will be asked to take several deep breaths at this time.

After catheter placement, you will either continue to receive nitrous oxide, or receive oxygen, based on your group assignment. Fluid will flow through the catheter and into your bladder until you feel you need to urinate, or "void". This phase of the procedure is called a "fill" and will be completed twice, according to standard procedure for UDS. Nitrous oxide or oxygen will continue until the filling and voiding phase is complete.

- There will be 3-5 minutes between fills. Regardless of the group you were assigned to, you will receive oxygen through the gas mask between fills.

The second fill will proceed in the same fashion as the first. At the start of the second fill, you will either continue to receive oxygen or receive nitrous oxide, based on your group assignment.

During both fills, you will be shown a page with a printed scale of 1 – 10. You will be asked to point to the number that represents the amount of pain and anxiety you are in at that time.

- We will also ask the practitioner performing your UDS how easy or difficult it was to perform

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the UDS.

After the UDS, you will be moved to a different clinic room. A study team member will ask you questions about your anxiety and pain before and after the UDS. Then, you will be asked to participate in a 15-20 minute structured interview with a qualified, trained member of study staff.

- The structured interview is designed to assess your experience with nitrous oxide during the UDS, in addition to any pain, anxiety or discomfort you may have felt. It is estimated to last approximately 15-20 minutes.
    - The audio from this interview will be recorded and stored in our secure database with your study records. We do not expect this file to contain any personal health information. The audio will be transcribed by a member of study staff and not sent out to any unauthorized third-parties for any reason. If you withdraw from the study, you may request for this file to be destroyed along with your other study records.

I agree to participate in an audio-recorded structured interview about my experience during UDS today: (please check to indicate your choice)

☐ YES

☐ NO

We expect you to be fully recovered from the effects of SANO within five minutes of stopping the gas. If you do not have a ride home after your UDS, the study team will administer two brief cognitive tests at the end of the study visit to assess your hand-eye coordination and ability to safely drive home.

- If you do not feel comfortable driving after your UDS, and you do not already have an escort planned, we will coordinate with you and your emergency contact to arrange a ride home.

4. Monitoring/Follow-Up Procedures. Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures. For this research study, the monitoring/follow-up procedures include:

    - A member of the research team will review your medical record and track your health status and any potential side effects 7 days after your UDS.

Study Participation Timeline	Prior to Day of UDS	Before UDS	During UDS	After UDS	7 Days After UDS
Informed Consent	X				

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Online Eligibility Questionnaire	X				
Pain and Anxiety Measurements		X	X	X	
Study Treatment			X		
Structured Interview				X	
Safety Follow-Up					X

Individual Research Results

Your study doctor will disclose any clinically relevant research results to you, including if we find any unexpected side effects of the nitrous oxide.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The research testing done in this study is just a stepping stone to learning more about the use of nitrous oxide during UDS.

While you should not expect to receive any results from the research testing, if we find that research results from your sample are of high medical importance, we may attempt to contact your medical provider to discuss the results. In some situations, follow up testing might be needed in a Clinical Laboratory Improvement Amendments (CLIA) certified clinical lab. You and your medical insurer may be responsible for the costs of these tests and any follow up care, including deductibles and co-payments. It is possible that you will never be contacted with individual research findings. This does not mean that you don't have or won't develop an important health problem.

Information and Biological Samples

Your information and biological samples will be used and shared with the researchers involved in this study to conduct the research. The consent form provides information on who will have access to identifiable information and identifiable biological samples during the study. We also want you to know that your information or biological samples may be stripped of any identifiers (for example your name, medical record number or date of birth) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. BIDMC researchers or other third party researchers may use your information and samples in other scientific research, product testing or commercial development. It is unknown whether a product will ultimately be developed from the research described in this consent form or from any such work that may be performed by BIDMC or other third parties receiving your information or biological samples. In signing this consent form, you are acknowledging and voluntarily consenting to the possibility that your information and biological samples may be used for commercial purposes. For example, your samples

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and information may be used to develop a new product or medical test to be sold. BIDMC and other researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.

If your identifiers are removed, we will not be able to destroy or remove your information or biological samples from distributed information or samples. As part of this research program and as further explained in this form, samples of your tissue and/or information about your medical history may be provided to other researchers and/or outside collaborators.

RISKS AND DISCOMFORTS

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

More Common
There are no common risks associated with the study.

Less Common
Some patients experience claustrophobia or difficulty breathing while breathing through a mask. During a previous clinical trial at BIDMC using nitrous oxide with a Nitrouseal ® mask, about 3 in 140 patients reported feeling uncomfortable breathing with a mask.

Rare
The following rare risks are associated with the use of nitrous oxide:

- About 1 in 200 patients experience mild nausea and vomiting.
- Other people have reported tachycardia, facial flushing, sweating, euphoria, drowsiness or lightheadedness when using nitrous oxide.

The following rare risks are associated with the use of oxygen:

Pure oxygen at high pressures can cause nausea, dizziness, muscle twitching. These side-effects are not expected at the concentration we will be administering.

There can be a concern of hypoxia or apnea during administration of any inhaled gas. This event has not been reported in scientific literature as a risk or side effect of nitrous oxide. However, continuous oxygen saturation and heart rate monitoring will be done by the member of the study team assisting with nitrous oxide administration to confirm patient safety.

A note about risk of urodynamic studies:
About 5-10% of patients experience dizziness or lightheadedness due to stress or discomfort of the procedure. Nitrous oxide is not expected to increase this risk.

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RISKS ASSOCIATED WITH SURVEYS/QUESTIONNAIRES

Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

Loss of confidentiality

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

CONFIDENTIALITY

Information learned about you during this research program will be maintained confidentially by the research staff as described in this form.

Information learned from your participation in this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your medical record may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However,

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your participation may help others in the future as a result of knowledge gained from the research. The results of the research may improve scientific understanding of the impact of self-administered nitrous oxide on urodynamic measurements.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the following option:

- You may undergo UDS per your urologist's standard of care. This does not include any pain control measures.

It is important to note that it is possible to get nitrous oxide at other clinical sites even if you do not take part in the study. Please be aware that not all doctors may agree to provide nitrous oxide, and health insurance companies may not pay for the drug when it is prescribed for UDS.

This research study is not meant to diagnose or treat medical problems not specifically stated in this informed consent document. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

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COSTS COVERED BY STUDY
You will not be charged for the medical gases, study device and treatment used as part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications used during this study that are considered standard for UDS.

CO-PAYMENT/DEDUCTIBLE STATEMENT
You will be responsible for any co-payments or deductibles that are standard for your insurance coverage.

PAYMENTS TO YOU:

You will not be paid for participating in this study. Your parking will not be covered, as there should not be any significant additional time relative to the parking you would have otherwise paid for the UDS.

COST OF RESEARCH RELATED INJURY:
If you are injured as a direct result of your participation in this study you should contact the Investigator at the number provided under the section "Whom to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. You or your insurance company will be billed for medical care and/or hospitalization related to this injury. You will be responsible for all co-payments and deductibles required under your insurance. BIDMC will consider reimbursement of injury related expenses not covered by your insurance on a case-by-case basis. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]
By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests) as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION
Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators,

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statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study, BIDMC's Division of Urologic Surgery, and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are

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many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Heidi Rayala, MD/PhD at 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: A PILOT STUDY TO ASSESS EFFECTS OF SELF-ADMINISTERED NITROUS OXIDE (SANO) ON URODYNAMIC STUDY (UDS) PARAMETERS
PRINCIPAL INVESTIGATOR'S NAME: HEIDI RAYALA, MD/PHD
PROTOCOL #: 2022P-000826

rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____