CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: **Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) – Physical Activity and Sleep Study**
Company or agency sponsoring the study: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Principal Investigator: James W. Griffith, PhD

Financial Interest Disclosure: If your doctor is also the person responsible for this research study, please note that he/she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

As a participant in the LURN study, you may be eligible to take part in the Physical Activity and Sleep Study, a research sub-study of the LURN study. Along with the information in this form, the consent form you signed to participate in the main LURN study applies to this sub-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 decide to not participate or 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.

The alternative to participating in this study is to not participate. Your care will not be affected if you decide to not take part in this study.

The purpose of this study is to measure the relationship between physical activity and sleep quality with urinary symptoms in people with urinary urgency. You are being asked to participate in this study because you are participating in the LURN study.

You will be given a physical activity and sleep monitor (Fitbit Charge 3 or similar) which can be linked to your smartphone. The Fitbit set up will occur during the baseline visit or remotely, depending on your preference. You must wear the Fitbit for a 2 week period starting at baseline prior to treatment and again at 3 months. During each 2 week period the Fitbit will be worn both day and night to collect the most information. The device is yours to keep once your participation in the study is completed.

During the 2 week period at baseline and at 3 months you will receive text message reminders to wear the Fitbit. You will also receive daily text messages during these time periods asking the number of nighttime voids you had. You will respond with a number response. Standard rates/fees for receiving text messages apply.

Text messages aren't encrypted, meaning if a text message is intercepted by a third party, the contents of the message can be read. For this reason, collecting personal health or identifying information with this method is prohibited. Upon consenting, you acknowledge that survey responses sent with the SMS text conversation method might be viewable.

A benefit to participating in this study is that you will be able to view your own activity and sleep information on the Fitbit app on your phone. The study may not offer any further benefits to you now but may benefit others in the future by allowing future researchers to use your study data that will be stored at the NIDDK Central Repository.

There can be risks associated with joining any research study. For this study the risk is that of a breach in confidentiality. To protect confidentiality, personal identifiers (other than gender) will be removed from all information stored in the study database. Your data will be sent to the NIDDK Central Repository, and may be shared with other researchers in the future for their research. Some agencies will have access to study records for monitoring and auditing purposes such as NIDDK, Arbor Research Collaborative, and the Institutional Review Board (IRB). These data will not contain your name or other direct personal identifying information. If a breach of confidentiality occurs, your participation could become known outside the research study. For additional confidentiality information, please refer to the main LURN study consent form.

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status
- All records relating to your condition, the treatment received, and response to the treatment
- Billing information

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on December 31, 2023. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

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 that you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- A monitor from the Data Coordinating Center may review your medical records and consent form(s) to check that the data that you provide are being recorded correctly and to monitor the progress and safety of the study.
- University and government officials and representatives from the NIDDK/NIH (study sponsor) or the Institutional Review Board for the study may review your medical records to make sure that the study is done properly.
- 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
- Your date of birth and gender must be shared with the Data Coordinating Center and the Data Safety and Monitoring Board, which oversees the safety of the study. This protected health information (PHI) will be used for statistical analysis of medical data.
- Insurance companies or other organizations may need the information in order to pay your medical bills or other routine medical costs not related to 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 Northwestern Medicine medical record.
- All data and samples are stored in a central repository under contract with NIDDK/NIH. The data and the samples do not contain any personal identification.
- If you receive any payments for taking part in this study, the Northwestern Medicine 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.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Also, Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire on December 31, 2023. Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:
PI's Name: James W. Griffith, PhD
Institution: Northwestern University Feinberg School of Medicine
Department: Department of Medical Social Sciences
Address: 625 N. Michigan Ave, 27th Floor, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Please contact the researchers listed below to:

- Obtain more information about the study or to offer input
- Ask a question about the study procedures or your rights as a research participant
- 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: James W. Griffith, PhD
Mailing Address: 625 N Michigan Ave, 27th Floor, Chicago, IL 60611
Telephone: 312-503-5345

Research Manager: Pooja Sharma
Telephone: 312-926-7846
Email: pooja.sharma@nm.org

You may also express a concern about this study by contacting the Institutional Review Board listed.
Ethical & Independent Review Services
816-421-0008
subject@eandireview.com
Reference E&I study 20112

If you are concerned about a possible violation of your privacy, contact the Institution's Privacy Officer at (312) 503-9338 or irb@northwestern.edu.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRB number (at the top of this form), and details about the problem. This will help Institutional officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

Consent

I have discussed this study, its risks and potential benefits, and my other choices with the study staff. My questions so far have been answered. If I have more questions or concerns about the study or my participation as a research participant, I may contact one of the people listed in the Contact Information section on the main LURN consent. I will receive a copy of this form at the time I sign it and later upon request.

☐ I consent to participate in this study. _____Initials

Legal Name in Print: _____

Signature: _____

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

Principal Investigator or Designee

I have provided this participant information about this study that I believe to be accurate and complete. The participant indicated that s/he understands the nature of the study, including risks and benefits of participating.

Name in Print: _____

Title: _____

Signature: _____

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

Witness Signature

I attest that the identity of the individual giving consent has been verified.

Printed Name: _____

Signature: _____

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