CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: **Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) – Physical Activity and Sleep Study, Project C: Controls**

Company or agency sponsoring the study: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Principal Investigator: Karl Kreder, MD,
200 Hawkins Drive, 3251 RCP, Iowa City, IA 52242,
319-356-4525

UIowa Study #202008471

KEY INFORMATION ABOUT THE RESEARCH STUDY

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.

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 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.

Approximately 9 people will take part in this study conducted by investigators at the University of Iowa and 200 participants are expected to participate (150 with LUTS and 50 controls). The study is being performed at six major university centers in the United States.

PURPOSE OF 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.

INFORMATION ABOUT STUDY PARTICIPATION

Your participation in this study will involve a 2-week period at baseline. You will be compensated and 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 at

baseline 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.

At 3 months you will be given a link to self-reported questionnaires. You will also be asked to complete a voiding and intake diary.

During each 2-week period 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.

INFORMATION ABOUT STUDY BENEFITS

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.

WHAT ARE THE RISKS OF THIS STUDY?

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.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.

- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

To protect confidentiality, personal identifiers (other than sex and 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.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) University of Iowa Health Care (UIHC) to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once UIHC has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, Ethical & Independent Review Services (E&I). The sponsor NIDDK may also inspect any part of your medical record for the purposes of auditing the conduct of the study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research related. Your signature on this Consent Document authorizes UIHC to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Karl Kreder, University of Iowa Care, 200 Hawkins Drive, 3251 RCP, Iowa City, IA 52242. However, we may still use your health

information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

WHAT IF I HAVE QUESTIONS?

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

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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

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): _____