

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:

J. Quentin Clemens, MD, MSCI, Professor, Department of Urology, University of Michigan
Anne Pelletier-Cameron, MD, FRCSC, Assistant Professor, Department of Urology, University of Michigan
John DeLancey, MD, Professor, Department of Obstetrics and Gynecology, University of Michigan
Dee Fenner, MD, Professor, Department of Obstetrics and Gynecology, University of Michigan
Giulia Lane, MD, Lecturer, Department of Urology, University of Michigan
Alyssa Gracely, MD, House Officer, Department of Urology, University of Michigan
Zhina Sadeghi, MD, House Officer, Department of Urology, University of Michigan

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 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.

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.

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:

J. Quentin Clemens, MD, MSCI, Professor, Department of Urology, University of Michigan
Mailing Address: Department of Urology, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-5759
Telephone: (734) 615-1262

Study Coordinators:

UROLOGY: Linda Drnek
Mailing Address: F7822D UH South, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-5759
Telephone: (734) 936-5754

GYNECOLOGY: Ashly Chimner

Mailing Address: L4100 Women's Hospital, 1500 East Medical Center Drive, Ann Arbor, Michigan 48109-0276

Telephone: (734) 763-6762

Email: LURN-Study@umich.edu

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 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 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): _____