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: Hing Hung (Henry) Lai, MD

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.

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Other research centers who are also working on the study and Arbor Research Collaborative for Health, which is the Data Coordinating Center.
- Study monitors and auditors who make sure that the study is being done properly.
- Government agencies and public health authorities, such as the Department of Health and Human Services (DHHS), the NIDDK, and advisors to these agencies.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed in the section above.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and text?

We would like to contact you by email and text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Study team may contact you by telephone or email to schedule appointments or remind you of an upcoming appointment and for study related questions/information.
- While wearing the monitor, you will receive daily texts regarding the number of times you had to get up to go to the bathroom during the previous night**.**

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address or phone number. To avoid this, we will send a test message to ensure we have the correct email address and telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**

Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**

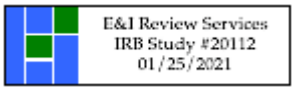
Initials **Initials**

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:	Dr. Hing Hung Lai
Mailing Address:	4960 Children's Pl, Box 8242
	St. Louis, MO 63110
Telephone:	314 454-8971

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



You may also contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

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): _____