INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Scheduled Awakenings for the Treatment of Nocturnal Enuresis

Benjamin Whittam, M.D

You and your child (if you are the parent or legal guardian of a patient) are invited to participate in a research study called Scheduled Awakenings for the Treatment of Nocturnal Enuresis. Your child was selected as a possible subject because they are between the age of 5 and 17 years old and have nocturnal enuresis (nighttime bed-wetting).

Please read this form and ask any questions you may have before agreeing to have your child be a part of the study.

The study is being conducted by Dr. Benjamin Whittam, M.D., a pediatric urologist at Riley Hospital for Children. It is funded by the Riley Children's Foundation.

STUDY PURPOSE

The purpose of this study is to determine the effectiveness of scheduled awakenings to potentially reduce the frequency of bed-wetting. A device created by Lully called the Sleep Guardian will be used to create these scheduled awakening. The device was initially developed for use in night terrors. During use, some users reported improvement in bed-wetting when using this device.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, your child will be one of 40 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, the study will move forward as follows:

The study will be 16 weeks long. The first 4 weeks of the study will be the I**nitial Phase.** During the initial Phase, we will collect baseline information about your child's nocturnal enuresis (bedwetting). The next 12 weeks will be the **Therapeutic Phase**.

After you enroll in this study, your child will be assigned to one of two treatment arms (groups) for the Therapeutic Phase. . In the first group, the treatment for your child's nocturnal enuresis will be behavioral modifications and the Lully device for six weeks followed by behavioral modifications only for a second six weeks. In the second group, the treatment will be behavior modifications only for the first six weeks followed by behavior modifications and the Lully device for the second six weeks.

During the initial and therapeutic phases of this study, you will be asked to enter responses daily into a Lully Study app. You will set up the app with the assist of the study team. The app will send a prompt each morning. to answer the questions: Did your child have a bed wetting episode last night? What time was it?

In a free text box you will be asked to add additional information to describe how wet your child was using the following 1-5 scale: 1- wet underwear; 2-wet underwear and damp pajamas; 3-soaked underwear, pajamas; 4-soaked pajamas, damp mattress; 5- soaked mattress

You will also be asked to complete two surveys at four time points throughout this study.

Initial Phase to establish baseline (4 wks)

1. You will complete a QOL survey, the KIDSCREEN 27 before starting the initial 4 week phase.
2. You will use a Malem Enuresis alarm daily during the first **2 weeks** of baseline data collection. This alarm will be loaned to you for use during this study.
3. You will complete responses to the daily questions prompted by the app, as described above.
4. You will be asked to complete the KIDSCREEN 27 and the Vancouver questionnaire at completion of the initial phase before starting therapeutic phase.

Therapeutic phase

1. You will complete the study phases in the order determined by your assigned treatment arm (group).
2. You will complete responses to the daily questions prompted by the app as you did in the Initial Phase.
3. You will be asked to complete the KIDSCREEN 27 and the Vancouver questionnaire at the end of the first six weeks and again after completing the second six weeks of this phase.

To use the Sleep Guardian, parents will need to own an iOS (Apple manufactured) device. You will be asked to download the Lully app from the Apple App Store. You will receive verbal and written instructions for the device set up and device use.

RISKS OF TAKING PART IN THE STUDY

While on the study, the risks are:

There are no physical risks known with either treatment option for this study. The safety of the Sleep Guardian has been extensively tested by the developer. Safety points are outlined on the product website at https://lullysleep.zendesk.com/hc/en-us. The Sleep Guardian cannot overheat. The Sleep Guardian has two features to prevent overheating. First, there's a heat sensor that turns the Sleep Guardian off if the temperature rises. Second, the Sleep Guardian shuts off after 3 minutes of use. The waves generated from the Sleep Guardian will not hurt a child. It uses Bluetooth Low Energy (BLE) to communicate to your phone. BLE is roughly 1,200 times weaker than the mobile phone radio waves present in your home today.

There is also a minimal risk of loss of confidentiality (privacy) concerning private health information that is associated with this research. Efforts will be made to keep your/your child's personal information confidential.

BENEFITS OF TAKING PART IN THE STUDY

Participation in this study will benefit the understanding of effective treatment options available to children with nocturnal enuresis. There is the potential direct benefit of nocturnal enuresis management with both treatment options.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in the study, you have the option of not participating. This will not affect your child's care in any way.

CONFIDENTIALITY

Efforts will be made to keep you and your child's personal information confidential. We cannot guarantee absolute confidentiality. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include the study investigator and his research associates, the IUPUI/IU Health Institutional

Review Board or its designees, and (as allowed by law) state or federal agencies (specifically, the Office for Human Research Protection).

COSTS

Taking part in this study will not lead to added costs to you or your insurance company. It is expected that participants return all equipment loaned to them for purposes of this study. This equipment includes the Malem enuresis alarm, the Lully Sleep Guardian, and the iPod if provided based on need and availability. It is asked that you return this equipment to the urology clinic at the end of the study.

PAYMENT

You will receive payment for taking part in this study. You will be compensated $1.00 for each day you reply to the daily questions prompted by the app. If you enter a response every day during the 16 weeks of data entry, you will have the opportunity to earn $112 for this portion of the study.

You will also be compensated $5.00 for each round of QOL surveys completed (2 surveys per round). If you complete all four survey rounds, you will have the opportunity to earn $20. At the conclusion of the study your total compensation earned will be calculated based on the number of activities you completed. This will be paid to the participant as an Amazon gift card.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Benjamin Whittam, M.D., at 317-944-8896. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please call the IU Human Subjects Office at 317-278-or 800-696-2949. After business hours, please call (317) 944-8896 and please ask to speak to the pediatric urologist on call.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University School of Medicine, Riley Hospital for Children or the Division of Pediatric Urology.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will also give consent for my child (under 18) to participate.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Youth Subject's Printed Name:_____

Youth Subject's Signature:_____**Date**:_____
(must be dated by the subject)

Printed Name of Parent/Guardian:_____

Signature of Parent/Guardian:_____**Date**:_____
(must be dated by the signee)

Printed Name of Second Parent/Guardian:_____

Signature of Second Parent/Guardian:_____**Date:**_____
(must be dated by the signee)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____