ALBANY MEDICAL CENTER
ALBANY, NY 12208

CONSENT TO TAKE PART IN A HUMAN RESEARCH STUDY

AND

HIPAA Authorization (Health Information Privacy Rights)

Title of research study: Transcutaneous electrical nerve stimulation (TENS) for the treatment of nocturnal enuresis in children (4961)

Principal Investigator: Adam Howe, MD

Site: Albany Medical College
Department of Surgery
Division of Urology
23 Hackett Boulevard, Albany, NY 12208

Study-related phone number: (518) 262-8579

Your child is being asked to take part in a multicenter research study because he/she has night-time bed wetting and behavioral modification has not helped.

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

What you should know about a research study

- We give you this consent form so that you can read about the purpose, risks and possible benefits of taking part in this research study. Please review it carefully.
- The main goal of regular medical care is to help each patient. The main goal of a research study is to learn things to help future patients.
- We cannot promise that this research study will help you.
- Just like regular medical care, your taking part in this research study can result in harmful effects that may be minor or serious.
- Someone will explain this research study to you. Feel free to ask all the questions you want before you make a decision.
- A research study is something you volunteer for. Whether or not you take part in this research study is up to you.
- You have the right to choose not to take part in the research study. Also, if you agree to take part now, you can change your mind later on.

- Whatever you decide it will not affect your access to health care, treatment and services not related to the research.

1 - Why is this research study being done and what is its purpose?

The primary objective is to determine whether using the TENS unit is a viable and safe alternative to medication for patients with night-time bed wetting. A TENS unit is a small controller box which sends an electric signal though wires to an electropad which transmits this energy through a patient's skin. Your doctor and his staff have the necessary equipment for this study.

This is a research study because usually patients are treated for night-time bedwetting with behavioral training (night-time alarms and timed voiding) and medications to help them with this problem. TENS therapy has been used in previous studies on children who leak urine during the daytime due to an overactive bladder but has not yet been used to treat patients with night-time bed-wetting. This study investigates whether it is effective to use a TENS unit to decrease the frequency of night-time bed-wetting.

2 - Who is doing the research study?

Dr. Adam Howe is in charge of this research study. We expect to enroll about 128 children in total to this study and about 50 children here at Albany Medical Center. If you choose to take part in this study, the study procedures will last for 90 days. It will include one month prior to treatment, the duration of the treatment with TENS therapy (30 days), and a one-month period of monitoring after completion of TENS therapy.

3 - What can you expect if you take part in this research study?

In this study, your child will be randomized. This means that your child will be assigned to a group by chance (like flipping a coin). S/he will have a 25% chance of being in any group. The groups your child can be assigned to are described in more detail below.

Transcutaneous electrical nerve stimulation (or "TENS" for short) is a form of neuromodulation which is commonly used for muscular pain disorders and physical rehabilitation. Neuromodulation is a novel treatment for voiding disorders and has become increasingly used in urology. This therapy acts on neural reflex loops between the spinal cord, central nervous system, and bladder after more peripheral nerves are stimulated to induce this reflex. This stimulation resets dysfunctional neural connections and accelerates proper brain-bladder nerve development. The transcutaneous method uses electrode pads (like a sticker on the skin) instead of more invasive needles or surgically placed implants that are used in commonplace urology practice and can be easily used for home therapy.

Your training for use of the TENS will proceed as discussed with your doctor.

After training, if your child is in **Group 1,** s/he will be in the suprapubic group. This means that the TENS therapy electrodes will be placed directly above the bladder, on the lower abdomen.

If your child is in **Group 2**, s/he will be in the posterior tibial nerve group. This means that you will place the electrodes for the TENS unit on the bottom of your child's feet.

If your child is in **Group 3**, s/he will be in the parasacral group. This means that you will place the electrodes on the lower back, just above the buttocks.

If your child is in **Group 4,** s/he will be in the group that places the electrodes on the scapula (shoulder).

You will be given a nightly voiding diary in which to record the number of times your child has an incontinent episode each night and the number of wet sheets each night, for the 30 days prior to starting the TENS therapy.

Next, you will receive the TENS unit for your child. You will place the electrodes according to the instructions for your assigned group at each night before bedtime for 15 minutes for a total of 30 days.

During your TENS unit training, you will be shown how to adjust the settings of your TENS unit. Your TENS unit will be set at a frequency of 10 Hz, pulse width of 260 seconds, and an intensity determined when you undergo teaching in the office based upon when your child feels sensitive to the TENS unit.

You will be given a voiding diary again for the month that you are using the TENS unit before bedtime. In this diary the number of incontinent episodes, the number of wet sheets per night, and the settings of the TENS unit, duration of therapy, and adverse reactions to the TENS unit will need to be recorded.

The month after completing the TENS unit therapy, you will again be given a voiding diary to record the number of incontinent episodes and wet sheets for 30 days after completing the TENS therapy.

You may be called during the TENS therapy month to ensure that you are using the TENS unit properly and to see if you have any questions or problems.

Patients and families will complete a questionnaire that asks questions about the child's quality of life at all of the time points described above.

Data including randomization number, age, gender, voiding diary data (wet nights, wet days, days with a bowel movement, days TENS was used correctly, a subjective wet scale, and any side effects), along with quality of life questionnaire scores will be collected in a REDCap database (which contains deidentified data) through the Feinstein Institute for Medical Research (Manhasset, NY).

4 - What are the risks and possible discomforts?

Adverse reactions to the TENS units

Your child will be closely monitored to ensure that s/he is not experiencing any adverse reactions to the TENS therapy. Risks can include pain, skin irritation, dermatitis, or burns. The most common reaction to the TENS unit is skin irritation related to an allergy to the self-adhesive electrodes.

Safe use of TENS units

You will be educated to safely use the TENS unit, including monitoring for signs of irritation, changing adhesive on the electrode pads after each use, securing the electrodes appropriately and alternating the side of each electrode in terms of laterality (for example, place the electrode pads on the right foot on one day, then on the left foot on the next day, etc.). Failure to adhere to safety guidelines could result in an adverse reaction to TENS therapy and dismissal from the study.

Malfunction of the TENS units

You will be taught how to monitor the TENS unit you are given for signs of malfunction that will require immediate maintenance.

Randomization

One of the randomized groups is a non-therapeutic group. Your child may be assigned to this group. Children in this group might have a risk such as skin reaction, without possible benefit.

There is a small risk of potential loss of confidentiality and resulting embarrassment.

5 - What are the possible benefits?

The possible benefits your child may experience from TENS therapy include avoidance of medications and reduced frequency of bedwetting while undergoing the TENS therapy. This study has the potential to positively impact the developmental, physical, and mental health of its participants.

6 - If you do not want to take part in the research study, are there other choices?

If you do not want to take part in this study, you can decline to do so. If you decline to participate in this study, the care your child receives will proceed as per current standards of care, with the use of bed wetting alarms, voiding diaries, and medication.

7 - If you have any questions or problems, whom can you call?

If you have any questions about the research study now or later, or if you think you have been injured by the research, you should call Adam Howe, MD or the Urology Research Office at (518) 262-8579. If you cannot reach Dr. Howe, you may call the Albany Medical College Office of Research Affairs at (518) 262-5182. You may also call this number if you have complaints about this research study, you believe you are not being treated fairly, or you have questions about your rights as a research subject.

If your child is hurt while participating in the study, s/he will receive medical care and treatment as necessary, however you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage.

8 - What information will be kept private?

We cannot guarantee privacy. However, efforts will be made to keep your personal information and other health information, including research study records and medical records, private. Organizations that may inspect and copy your private information include the Food and Drug Administration, the Department of Health and Human Services, the New York State Department of Health and Albany Medical Center. You will be identified as a research participant for medical records and billing purposes.

We plan to publish the results of this research. However, your name and any other identifying information will be private and will not be able to be linked to information found in the study. In the final publication, there would be no way to identify your information within the overall study information.

Authorization (Permission) to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

If you have questions about your privacy rights, please call the AMC Research Privacy Officer at (518) 262-0671.

What information about you may be used and given to others?

If you choose to be in this study, the study doctor, his/her study team including any new members of the study team in the future, and others who need it will have information about your past or present health care or condition or treatment, that identifies or can be used to identify you. This information is called "protected health information" or just "health information" for short. Health information includes both your medical information and information such as your address, where you work, your date of birth, and other similar personal information.

Your health information that may be used for this study can be in different forms and may include:

- Written information such as what is in your medical chart, or the record of your study visits
- Electronic information which is information stored in computer systems, such as billing data
- Verbal information such as in phone calls made as part of this research study

Who will be able to use your health information and give it to others?

The physicians involved in the study along with research coordinators and research staff will have access to the health information gathered. Some basic information may need to be shared with Albany Medical Center and Institutional Review Board as part of their oversight of the study.

Otherwise, individual patient information will not be shared with people who are not involved in the study. The information gathered as a whole in the study will be shared with other physicians at publication and at medical meetings. Your individual data will never be shared in these ways except when part of the overall group data.

Who will be able to get your health information and use it?

Information about your health that might identify you may be given to:

- Albany Medical Center
- The Albany Medical Center Institutional Review Board (IRB)

If you give written permission to release your health information to certain parties of your designation, then information may be shared and no longer be protected by the privacy regulation.

Will you be able to see your research records?

If your child's research records are used for decisions related to clinical care, then you have the right to review this information and request changes. This is limited to information about your child's treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this research information only after the study analysis is complete.

Why are others able to get your information and for what purpose or purposes will the information be used?

Information about you and your health that might identify you may be given to others to carry out the research study.

The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed for those purposes.

The information may be reviewed by a group of people called the IRB. The IRB is responsible for protecting your rights and welfare and is not involved in the conduct of the clinical study.

When and how can you cancel your permission?

You may cancel your permission for us to use and disclose your health information at any time. You do this by sending written notice stating you wish to cancel your permission. Send this to the study doctor. If you cancel your permission, you will not be able to continue being in this study.

When you cancel your permission, no new health information that might identify you will be gathered after that date. Information gathered prior to your cancellation of permission may still be used and given to others. This would be done to account for your withdrawal.

When will the research end and when will your health information no longer be used?

There is no limit on the length of time we will keep your child's information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

What if you don't want to give your permission to be included in the research and don't want anyone to give out and use your health information?

If you do not give us permission and sign the permission (authorization) form, you will not be able to be in this research.

You can give us permission to use and give out the health information listed above for the purposes described above by signing this permission (authorization) form.

9 - Can your taking part in the research end early?

You may decide not to continue in the research study at any time and it will not affect your access to health care, treatment, and services not related to the research.

We will tell you about any new information that may affect your health, welfare or choice to stay in the research.

It is also possible that your participation in this study may end without your consent. Additionally, after the 30 day evaluation you could be considered ineligible in which case the investigators will let you know that. This decision may be made by a research member.

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for your visits,
- it is not in your child's best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

10 - What else do you need to know?

You will not be paid for your participation in this study.

You will not have any costs from being in this study.

The investigator does not receive any money if you take part in this study.

You will need to return the TENS unit after the 30-day period of use.

DO NOT SIGN
LATER THAN EXPIRATION DATE OR
IF THERE IS NO EXPIRATION DATE ➡

ALBANY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
APPROVAL EXPIRES:
AUG 26, 2020
ISSUE DATE: 08/26/2019

PERMISSION OF RESEARCH SUBJECT'S PARENT(S) OF MINOR OR LEGAL GUARDIAN(S) OF PERSON AND HIPAA AUTHORIZATION

To be completed by Principal Investigator/designated member of research team:

☐ Check here if second parent of minor or legal guardian is deceased, unknown, incompetent, or not reasonably available.
☐ Check here if only one parent of minor has legal responsibility for the care and custody of the child.

To be completed by IRB Office:

☐ Check here if permission of second parent of minor or legal guardian is not required by the IRB.
☐ Check here if assent is not required by the IRB because the subject is not capable of assent.
☐ Check here if assent is not required by the IRB because the research holds out prospect of direct benefit that is important to the health and well-being of the subject and is available only in the context of research.
☐ Check here if assent is not required because the requirement for assent was waived by the IRB.

Subject information:			
Name (print or type)			
Approval of parent of minor or legal guardian:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
Relationship	☐ Parent of minor ☐ Legal Guardian		
Approval of parent of minor or legal guardian:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
Relationship	☐ Parent of minor ☐ Legal Guardian		
Consent obtained by:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)	Title		
Witness:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
A witness is required when the parent of minor or legal guardian cannot read and the consent document was read to the subject. The sponsor may also require a witness.			
We will give you a signed and dated copy of this Consent Form.			

DO NOT SIGN
LATER THAN EXPIRATION DATE OR
IF THERE IS NO EXPIRATION DATE ➡

ALBANY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
APPROVAL EXPIRES:
AUG 26, 2020
ISSUE DATE: 08/26/2019

PERMISSION OF RESEARCH SUBJECT AND HIPAA AUTHORIZATION

Approval of research subject:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
Consent obtained by:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)		**Title**	
Witness:			
Signature		**Date Signed**	
		Time Signed	
Name (print or type)			
A witness is required when the subject cannot read and the consent document was read to the subject. The sponsor may also require a witness.			
We will give you a signed and dated copy of this Consent Form.			