

Consent and Authorization Document

Study Title: Patient Reported Outcomes for Bladder Management in Neurogenic Bladder and Spinal Cord Injury

BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or study staff if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of the study is to compare patient reported quality of life between different bladder management methods in patients with neurogenic bladder and or spinal cord injury. This information is meant to help guiding patients and doctors in shared-decision making about how to manage their bladders.

Nearly 80% of spinal cord injury patients, as well as many other patients with neurologic conditions, have urinary issues, like urinary leakage or increased frequency of urination, which can have a significant burden on patients' physical health and quality of life. Inappropriate management can cause hospitalizations and serious complications like urinary tract infections and kidney damage. Most physicians believe the best "medical" bladder management is clean intermittent catheterization, where patients or caregivers perform regular urethral catheterization to empty the bladder. However, this task may be difficult for patients to perform independently due to physical limitations or its inconvenience. Alternatives strategies to intermittent catheterization include an indwelling catheter that drains the bladder continuously or reconstructive surgery (to divert urine to a different location so patients can intermittently catheterize independently). Patients believe that both independence and ability to carry out daily activities are just as important as physical health in selecting the right bladder management strategy and there is very little data that helps patients and doctors decide the best management strategy for individuals.

The Research Team agrees that patient centered outcomes, or patients' actual report of how different management strategies affect their quality of life is of utmost importance in deciding between different bladder management choices. We are conducting this study to collect patients' opinions about their bladder management since this has never been done before on a large scale.

This study is being conducted by Dr. Jeremy B. Myers at the University of Utah Urology Division.

STUDY PROCEDURES

Observational trial:

If you agree to participate in this trial, you will have about a 30-minute visit with a clinician like a nurse, physician, or physician assistant, or other study personnel, who will obtain your history. If you are



unable to come to the University of Utah, then this 30-minute visit will be conducted over the phone at a time that is convenient for you. You will be asked very routine questions about your past health, medication use, surgical history, and specifics related to your bladder management. At the end of this visit you will answer questions on a tablet about your quality of life, pain, and bladder management. These additional questionnaires do not take more than 30 minutes to answer.

You will continue to have routine follow up with your urologist or physical medicine and rehabilitation clinician. When you are in to see these physicians you will be asked about changes in your bladder management and health. You will also be asked to answer the same types of questions about your quality of life that you answered before. During the course of the study, the questionnaires and inquiries about changes will be emailed to you or will be read to you over the phone by study personnel at 3 month intervals for up to 1 year, or until enrollment in this study is complete (enrollment might be completed in less than 1 year). At the end of 1 year or at the end of the study, whichever comes first, there is an Exit Interview which is a questionnaire that will ask you questions about any changes in your bladder management, any surgeries you've had that might have affected your bladder management and any complications you might have had with your bladder management over the last year. This Exit Interview can be done on your computer with a link to the questionnaire or the study personnel can ask you the questions over the phone; whichever you prefer. This Exit Interview will take approximately 15 to 20 minutes. Study personnel may also contact you during the course of the study.

Participation in the study will last for up to 1 year and you can withdraw from the study at any time.

RISKS

There are no medical procedures or changes in your care associated with the study and no risk to your health, which could occur from the study. Your health information will be kept secure, just as it is in the hospital for your normal care and will never be shared in a way where your identity could be discovered by people not working on the study.

BENEFITS

The benefits are to all patients with neurogenic bladder. The data collected from this study will allow us to help clinicians (like doctors or nurses) and patients make more informed decisions about their bladder and health care.

ALTERNATIVE PROCEDURES

You may choose not to participate in this study. If you do not want to take part in the study, your doctor will treat you no different than if you are enrolled in the study.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Elizabeth Lignell, B.S., CCRA, CCRC (study coordinator) at (801) 213-2780. If you are calling after normal business hours, you can call (801) 581-2121 and ask for the Urology Resident on call. This last number is answered 24 hours a day.



Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

RIGHT OF INVESTIGATOR TO WITHDRAW

Your study doctor has the right to withdraw you from the study at any time, with or without your consent. This may be done if he determines that you are not a good candidate for the study.

There should be no foreseeable consequences of withdrawal from the study and you would be treated per our standard of care for your condition.

COSTS AND COMPENSATION TO PARTICIPANTS

There should be no costs to you for participation in this study. You will be compensated \$50 after enrollment in the study and the completion of the first set of questionnaires. If you complete all questionnaires during your study participation, you will be compensated an additional \$50. The \$50 is in the form of a gift code to use at Amazon.com or a \$50 gift card to Walmart. Upon completion of the Exit Interview, you will be given an additional \$20 gift code to use on Amazon.com or a \$20 gift card to Walmart.

NUMBER OF PARTICIPANTS

We expect to enroll 1,500 – 1,800 participants at the University of Utah. This study is a national study, and will also be conducted at Universities of Minnesota, Michigan and Western Ontario

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, medical record number, address telephone number, and email address

- Related medical information about you like past medical history, specifics of current urologic problems, physical exam findings, medications, previous surgeries, the details of treatments you receive for your neurogenic bladder.
- Results of lab tests and urine cultures, radiology x-rays such as ultrasounds, x-rays, and CT scans.
- The outcomes of several questionnaires related to bladder management, quality of life, and pain

In some cases, the study personnel will need to obtain information from your health care provider, about the extent of your spinal cord injury and about your current medical exams and treatment. By signing (either electronically or by hand) this consent form, or by verbally consenting to participate in this study, you are giving your permission for the study personnel to request these medical records and information.

Please contact the study personnel anytime you have been hospitalized for any reason. The study personnel will request information from any hospitalization that occurs while you are participating in this study. By signing (either electronically or by hand) this consent form, or by verbally consenting to participate in this study, you are giving your permission for the study personnel to request this information.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
 - Members of the research team and University of Utah Health Sciences Center
 - The University of Utah Institutional Review Board (IRB) who reviews research involving people to make sure the study protects your rights.
- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a



code number, so they will not know your identity.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

