Permission to Take Part in a Human Research Study

Title of Research Study: ***Self-Catheterization Mirror System for Female Patients***

Investigator: Megan O'Brien, PhD

Supported By: This research is supported by the Shirley Ryan AbilityLab.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this study because you complete self-catheterization.

What should I know about a research study?

Someone will explain this research study to you. Whether or not you take part is up to you.

You can choose not to take part.

You can agree to take part and later change your mind. Your decision will not be held against you.

You can ask all the questions you want before you decide.

Why is this research being done?

Many female patients have difficulties with self-catheterization. Mirrors currently used for this procedure have limited stability and visibility to easily view the urethral opening during catheterization, particularly for individuals with motor impairments. This can be especially frustrating because catheterization is performed frequently throughout the day and may need to occur at home or in public facilities.

The purpose of this study is to test the safety and efficacy of a modified self-catheterization mirror system for female patients. The modified self-catheterization mirror system is a product to help female patients with a range of motor abilities catheterize themselves in various postures and settings. Namely, the system offers (1) an alternative way to hold the mirror, by suspending it between the legs rather than attaching it to the toilet, and (2) lights that can be turned on for improved visibility during the self-catheterization process.

The modified self-cathterization mirror system for female patients is experimental and is not an FDA-approved medical device.

How long will the research last and what will I need to do?

We expect that you will be in this research study during two weeks of your inpatient rehabilitation stay at the Shirley Ryan AbilityLab.

You will be asked to use a standard catheterization mirror for one week (Phase 1) during self-catheterization followed by using the modified self-catheterization mirror system for an

additional week (Phase 2). The modified mirror is shown below. Study staff will help you practice setting up and using this modified mirror in 1-2 training sessions before you are asked to use it for self-catheterization.

During the two weeks, each time you complete self-catheterization, you will be asked to provide details about which mirror you used, the position you were in: seated, reclined, or standing, and approximate amount of time needed to complete the self-cathing. The purpose of providing these details is to help us understand the situation in which you used the mirror, and its effectiveness for helping you self-catheterize in those situations. At the end of each week, you will complete a questionnaire about your experiences using the assigned mirror.

The modified self-catheterization mirror system includes the standard mirror, held in a surrounding case, with adjustable straps for suspension between the legs and LED lights that can be turned on/off.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

The risks from this study include:

- Skin breakdown from mirror placement in lower-body positioning
- Muscle soreness
- Possible contribution to urinary tract infection (UTI)
- Possible embarrassment or uncomfortableness

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include making the self-catheterization easier. The main benefit of participation in this study is understanding the real-world challenges of self-catheterization, which may help other people through future development of devices and procedures.

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What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-238-2289.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect that up to 30 patients at the Shirley Ryan AbilityLab will be in this research study.

What happens if I say "Yes, I want to be in this research"?

The study team will show you the two mirrors (standard and modified) that you will be using during self-catheterization and answer any questions you may have about their use. You will use the standard mirror for 1 week, and then you will be asked to use the modified mirror for 1 week. The standard mirror will be available to you throughout the study for use as needed.

Before using the modified mirror, study staff will demonstrate the attachment of the mirror and help you practice setting it up in different positions (for example, when seated, reclined in bed, or standing) during a single training session. If you are unable to achieve and maintain a position independently or with minimal assistance, the training in that position will be skipped. Training will be considered successful if you can set up the modified mirror 3 times independently in all possible self-catheterization positions. At the end of the training session, we will ask you if you would feel comfortable using the mirror independently.

A subsequent training session will be scheduled if you need additional practice with the mirror system. If you are having difficulty setting up the modified mirror 3 times independently in the possible self-catheterization positions, or if you do not feel comfortable using the mirror independently, you will be asked to fill out a questionnaire regarding your experience with the device and study procedures will end.

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Immediately following the completion of a successful training session with the modified mirror, you will begin the 1 week of using the modified mirror for self-catheterization. You will continue to have access to the standard mirror during this phase, and will be encouraged to use the standard mirror instead for any trial if needed for successful self-catheterization.

You will complete a Self-Catheterization Log throughout this study to identify the mirror type, position and approximate time needed to complete catheterization. Following each week of attempted use of each mirror, you will complete a brief questionnaire about that mirror.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Use the two mirrors for self-catheterizing for two weeks during your inpatient stay
- Complete the Self-Catheterization Log and end-of-phase mirror questionnaires
- Communicate with research personnel if you have any questions, pain, or injuries.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the research study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collecting data regarding your routine medical care. If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

A possible risk is discomfort, skin pressure/friction, or bruising caused by the modified mirror, which has the potential to lead to skin breakdown or abrasions. This risk will be minimized by a thorough skin check performed by clinicians before and after device use, and application of foam dressings or bandages as needed. Use of the modified mirror will be discontinued for any participant with skin breakdown.

There is a risk of muscle soreness from being in a certain position for a prolonged period of time during the self-catheterization process. Clinicians will monitor subject activity and subjective reports of pain or discomfort throughout the process. Assisted repositioning and/or rest periods will be provided as needed.

Risk of a urinary tract infection (UTI) due to use of the device. This risk will be minimized by emphasis of utilizing a sterile environment during self-catheterization and following hospital protocols regarding hygiene and cleanliness of devices and equipment.

Embarrassment or discomfort discussing self-care may be associated with this study. All staff members assisting with this study are trained professionals and familiar with the intermittent catheterization process.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval.

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

What else do I need to know?

You will be paid $20 for participating in this research study.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

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Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See “Tips for Using the Attached ClinCard” for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

Results of physical examinations
Medical history
Records about study
devices Billing information

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH). Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator’s office].

Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRAlab), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH),

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Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this research study may be tracked in an electronic database and may be seen by investigators running other studies that you are enrolled in and by your healthcare providers.

Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.

Other University research centers and University contractors who are also working on the study

Study monitors and auditors who make sure that the study is being done properly Government agencies and public health authorities, such as the Food and Drug

Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

PI's Name: Megan O'Brien, PhD
Institution: Shirley Ryan AbilityLab
Department: Max Nader Center for Rehabilitation Technologies and Outcomes, Center for Bionic Medicine
Address: 355 E. Erie Street, Suite 1402, Chicago, IL 60611

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent