Explanation of Research (Consent Form)

Study Title: A Web-Based Self-Management Intervention for Intermittent Urinary Catheter Users (Pilot study)
Principal Investigator: Mary H. Wilde, PhD, RN

This is a copy of the information provided verbally by telephone and available on the study website when the research study was initially described.

Purpose of Study
This study involves developing and testing a new web-based approach to self-management of an intermittent urinary catheter in people with Spinal Cord Injury (SCI). You are being asked to be in this study because you use an intermittent catheter for bladder management. The study is conducted by Mary Wilde, PhD, RN, a nurse researcher at the University of Rochester, School of Nursing. Dr. Wilde has done 8 other studies related to urinary catheter care in the past. We are very interested in trying to improve the lives of people who use intermittent catheters, and there is a need to know whether better self-management of an intermittent catheter can improve bladder health and quality of life.

About 30 people with SCI using an intermittent catheter across the USA will be in this study, recruited mostly through the Internet. Your involvement and testing of this program will help us determine its feasibility and value for a larger study in the future.

Description of Study Procedures
This program includes use of web-based materials, a urinary diary and educational booklet, a trained study nurse who will call you on the phone three times in a three month period, and an online peer forum (discussion). Your participation in the study will last about three months.

Specifically you will be asked to:
- Try out the online self-management program on your home computer and your mobile phone device if you have one and wish to try that.
• Work with a trained study nurse in three telephone consultations.
• Participate in an online forum with peers using an intermittent catheter.
• Complete two online questionnaires, one at the beginning and a second after you have completed the self-management program.
• Also a brief audio-taped phone call interview at the end of the self-management program.

Study Nurse Consultations and Self-management Program
During the first telephone consultation, you will be taught how to use an online urinary diary and personal data base for self-monitoring your fluid intake and urine output (I & O). You will be asked to do this initially for three days. You also will be taught to use an online secure personal data base for your catheter related information, such as tracking I and O over time. You will be sent containers in the mail to measure your fluid intake and urine output. The study nurse will be available for email questions during the time of your study participation.

During the second telephone consultation a week or two later, the study nurse will review an online educational booklet and discuss your intermittent catheter self-management needs and interests with you, as well as online resources (websites) that might be of value. If you wish, we will mail you hard copy versions of the diary and educational booklet, as these might be helpful to you and anyone else who assists with your catheter related needs.

At the third telephone consultation at about two months, the study nurse will help you fine-tune your catheter self-management plans, evaluate how well your strategies are working, and consider other activities or approaches as needed. Each phone call should take about 45-75 minutes.

Peer Support
There will be online peer forums with the other people in this study. The forums are to provide peer support from others with SCI who are living with an intermittent catheter. Each person in the study may participate in the forum during the three months of their self-management program. When about three or four people are enrolled in the program, the forums will begin. The composition of the group will change as new people join and others finish the program. Therefore, we anticipate that the forum will have about 8-10 persons at a time. Two peer leaders will help moderate different forums as needed. The persons in each forum will determine how long the forum will take place and about the level of interactivity, such as real time or virtual, during the study. The study nurse will be involved at least once a week to help moderate the forum and answer questions.

Online Questionnaire and Interview(s):
1. The online questionnaire involves specific questions about your intermittent catheter practices and general information about you, like your age. The
questionnaire should take about 15-30 minutes to complete. You will be given verbal and/or email assistance from the Research Assistant for any issues related to completing the questionnaire.

2. At three months from starting, you will be asked questions about the program as a part of your three months’ online questionnaire. You also will be called on the phone for a short final evaluation discussion about the program--what you liked and disliked about the program and for suggestions for improvement.

Confidentiality of Records and HIPAA Authorization

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy health information after the study ends, but not until the study is completed. If you would like a copy of the Strong Health HIPAA Notice, please ask the investigator (Dr. Wilde) for one. Results of the research may be presented at meetings or in publications, but your name will not be used.

We will use your health information from the questionnaire, interviews, and focus group. The questionnaires include demographic questions (such as your medical diagnosis) and questions related to catheter care practices (such as, how often you catheterize and how you manage catheterization issues). For the final phone call interview at the conclusion of your self-management program, you will be asked questions about your experiences of being in this program, how the online and phone components worked, how it affected your catheter practices, and for suggestions to improve the program. All of the information collected for this study will be analyzed as group data, and your name will not be used in any reports at professional conferences or research articles. Also, the data we collect will have only an identification number on it, not your name.

Risks of Participation

The risk to you of participating in this study is minimal. There is a chance that you might think about your intermittent catheter problems more frequently since we would be talking with you about it and keeping you in touch with others having similar issues. You may feel embarrassed by some of the questions regarding the management of your urinary catheter. Dr. Wilde has extensive experience with people like you who use an intermittent catheter, and she and her staff will be sensitive to the private nature of conversations involved in this study. You may experience mild stress if you have difficulty with completing the online surveys or urinary diary. Our research staff will assist you with completing these forms if needed. There is a very small chance of
infection if you spill your urine when measuring it; the risk of infection is the same as you have with the daily care of your catheter. To minimize this, the Study Nurse, who is a registered nurse (RN), will teach you how to measure the urine without spilling and provide non-latex gloves to use while measuring your urine. No discomforts are expected as a result of any of the activities in this study.

**Benefits of Participation**
Benefits for this study include learning whether this program is effective in promoting better bladder health and whether people perceive benefit from the individualized self-management teaching. However, no direct benefit to you can be assured.

**Compensation**
All of the activities will be scheduled at your convenience. You will be paid $50 for your participation in this study. You will be paid in a $25 check that will be mailed to you after you complete the online questionnaire at the beginning of the study and another $25 check will be mailed to you after the online questionnaire and short phone call at three months.

**Voluntary Participation**
Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. Also, you may stop the questionnaire or interview at any time if you decide to not participate in the study.

**Contact Persons**
If you have any questions about the study, or if you feel that your participation has resulted in any emotional or physical discomfort, please call the principal Investigator, Dr. Mary Wilde, at 585-275-9682 or toll free at 877-345-9682.

If you have any questions about your rights as a research subject, or any concerns or complaints, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315, Telephone (585) 276-0005, for long-distance you may call toll-free, (877) 449-4441. You may also call this number if you cannot reach the research staff and wish to talk with someone else.

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**Person Obtaining Verbal Consent**
I have read this form to the research subject. If desired, I will provide the research subject with a signed copy of this form. An explanation of the research was given and questions from the research subject were solicited and answered to the research
subject’s satisfaction. In my judgment, the research subject has demonstrated comprehension of the information.

________________________________________________________________________  Print Name and Title
________________________________________________________________________  Signature
________________________________________________________________________  Date