Clinician Participant Consent

Consent Template - Online Research
IRB Protocol Number: 2023H0166
IRB Approval date: 06/12/2023
Version: 1 The Ohio State University Informed Consent- Online Research Study Title: Feasibility Testing of a Urinary Drainage Bag Securement Device to Improve Patient and Clinician Ambulation Experiences Principal Investigator: Karen Meade, MS, APRN-CNS, AGCNS-BC, OCN Sponsor: None

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: The purpose of this study is to determine the feasibility of the Bag Below Bladder (B3) Buddy in securing urinary drainage bags while patients ambulate.

Procedures/Tasks: After a short in-service on how to use the B3 Buddy, you will secure the patient's urinary drainage bag with the B3 Buddy and assist them in walking the length of a hallway outside of the patient's room. You will be instructed to empty the urinary drainage bag prior to assisting the patient in walking and that no parts of the urinary drainage bag or tubing touch the ground. After completing the walk and returning the patient to their room, you will remove the B3 Buddy and secure the urinary drainage bag appropriately. A member of the research team will email you a link to complete a 10-question survey about your experience with the B3 Buddy. If a response has not been received in three days, you will receive a reminder email.

Duration: Your total time participating in this study will be approximately 20 minutes.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: There is a risk of the device unclipping or untethering from its secured surface, causing the urinary drainage bag to fall on the ground. This is no different from the standard of care. To the best of our knowledge, there are no other safety concerns. The benefits of participating in this study are to provide an opportunity to utilize a device that is not yet available for public use and provides a simple solution for keeping a urinary drainage bag at the optimal position while ambulating.

Confidentiality: We will work to make sure that no one sees your online responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Also, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

Office for Human Research Protections or other federal, state, or international regulatory agencies; The Ohio State University Institutional Review Board or Office of Responsible Research Practices; Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Future Research: Your de-identified information may be used or shared with other researchers without your additional informed consent.

Incentives: There are no incentives for participating in this study.

Participant Rights: You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Karen Meade, Principal Investigator at 614-366-5060.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent:

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.