Patient Participant- Combined Consent & HIPAA Authorization

CONSENT & AUTHORIZATION
IRB Protocol Number: 2023H0166
IRB Approval date: 06/12/2023
Version: 1The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization
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. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate. Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status. You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research. You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.
This study is being performed to determine if an invention, called the Bag Below Bladder (B3) Buddy, works in securing urinary drainage bags while patients walk. There are currently no devices designed to secure a urinary drainage bag, also known as a foley bag, while a patient walks. To address this, a urinary drainage bag securement device called the B3 Buddy was invented by the research team. This study will allow the research team to understand if the B3 Buddy design is acceptable and usable to the end users.

1. Why is this study being done? To determine the feasibility of the Bag Below Bladder (B3) Buddy in securing urinary drainage bags while patients walk.

2. How many people will take part in this study? The research team hopes to accrue a total of 20 patient participants and 20 clinician participants.

3. What will happen if I take part in this study? After you participate in a short in-service on how to use the B3 Buddy, your clinician (e.g., nurse, patient care associate, physical therapist, occupational therapist, therapy assistant) will secure your urinary drainage bag with the B3 Buddy and assist you in walking the length of a hallway outside of your room. They will ensure that the urinary drainage bag is emptied prior to your walking experience. They will also ensure that no parts of the urinary drainage bag or tubing touch the ground while you walk. After completion of the walk and returning to your room, your clinician will remove the B3 Buddy and secure the urinary drainage bag appropriately. The research team will provide you with an electronic tablet to complete a 4-question survey about your experience with the B3 Buddy.

4. How long will I be in the study?
Your total time participating in this study will be approximately 17 minutes.

5. Can I stop being in the study?
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.

6. What risks, side effects or discomforts can I expect from being in the study? 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.

7. What benefits can I expect from being in the study?
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.

8. What other choices do I have if I do not take part in the study?
You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you do not participate in the study, clinicians will secure the urinary drainage bag with the current standard of care (e.g., holding the urinary drainage bag by hand, using a device not meant to secure the bag such as a tourniquet or glove).

9. What are the costs of taking part in this study?
There is no cost to participating in the study.

10. Will I be paid for taking part in this study?
There are no incentives in participating in this study.

11. What happens if I am injured because I took part in this study?
If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?
If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

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 research participants.

13. Will my de-identified information (and bio-specimens) be used or shared for future research?
Yes, it may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?
Efforts will be made to keep your study-related information confidential. However, 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;
U.S. Food and Drug Administration;
The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
The sponsor supporting the study, their agents or study monitors; and
Your insurance company (if charges are billed to insurance).

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?Past and present medical records;
Research records;
Records about phone calls made as part of this research;
Records about your study visits;
Information that includes personal identifiers, such as your name, or a number associated with you as an individual

II. Who may use and give out information about you?
Researchers and study staff.

III. Who might get this information?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;
If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
Others: External collaborators that are part of the research team may have access to de-identified health information.

IV. Your information may be given to:The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
Governmental agencies in other countries;
Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?To do the research;
To study the results; and
To make sure that the research was done right.

VI. When will my permission end?
There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?
Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?
Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?
For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact Karen Meade, Principal Investigator at 614-366-5060; karen.meade@osumc.edu; 460 W. 10th Avenue Columbus OH, 43210 Floor 20, Room B2004B.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ¬the HIPAA Privacy Officer, 614-293-4477, privacyoffice@osumc.edu, 650 Ackerman Rd, Columbus, OH 43210.

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.

Signing the consent form
I have read (or someone has read to me) this form 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 signing this form. I will be given a copy of this combined consent and HIPAA research authorization form.

I voluntarily agree to participate in this study.	◯ Yes ◯ No
Full Name of Subject	_____
Signature	_____
E-mail	_____
Date and time	_____

AUTHORIZED AGENT (when applicable)

Is there an authorized agent present?	◯ Yes ◯ No
Printed name of person authorized to consent for subject (when applicable)	_____
Signature of person authorized to consent for subject (when applicable)	_____
Relationship to the subject	_____
Date and time	_____

INVESTIGATOR/RESEARCH STAFF

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent

_____

Signature of person obtaining consent

_____

Date and time

_____

Adapted from Combined Consent & HIPAA Authorization Template

(http://orrp.osu.edu/irb/investigator-guidance/consent/)