Study Title: Preventing Hospital-Acquired Disability: An Intervention to Improve Older Adult Patient Ambulation

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Subject Identification # _____

[REDACTED SITE 1] and University of Wisconsin
Consent to Participate in a Research Study

Study Title	Preventing Hospital-Acquired Disability: An Intervention to Improve Older Adult Patient Ambulation [sponsor protocol ID#1R01HS026733]
Study Investigators	Barbara King, PhD, APRN-BC, FAAN - University of Wisconsin-Madison Phone: 608-263-5319 Linsey Steege, PhD – University of Wisconsin-Madison Phone: 608-263-5191 [REDACTED SITE 1 contact]
Sponsor	Agency for Healthcare and Quality

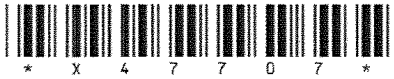
Why am I being asked to participate?
Lack of walking during a hospital stay has been shown to cause weakness and walking problems for older adults after hospital discharge. We are interested in testing a new program that will help older adults maintain their walking ability during a hospital stay. You are being asked whether you would like to voluntarily take part in a research study about helping older adult patients walk during their hospital stay. You are being invited because you are an older adult patient who is receiving care on an inpatient unit at [REDACTED SITE 1] selected to participate in the study.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?
A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, researchers need volunteers to participate in research studies. We will explain the process and help you decide if you want to participate.



What is the purpose of this study?
The purpose of this study is to find out if a new program helps patients walk during their hospital stay.

Who is sponsoring this study?
The sponsor for this study is the Agency for Healthcare and Quality. The sponsor pays for Dr. Steege and Dr. King and [REDACTED SITE 1] to run the study.

Where will this study take place?
This study will take place on an inpatient unit at [REDACTED SITE 1] selected to participate in the study and during with three follow-up contacts with the Research Team.

How many people will take part in this study?
Drs. King and Steege and their team expect to have 320 patients participate in the study.

What is involved in the study?
If you decide to take part in the study, you will be asked to do the following:

Participate in a brief (10 minute) visit to start and when you are ready to leave the hospital:

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking when you arrive at the hospital and before you go home.
2) Do a short test of your walking speed when you arrive and before you go home.
3) Allow us to collect information from your medical record including age, gender, race, ethnicity, reason for admission, past medical history of health problems, albumin level, where you lived before you entered the hospital, your ability to complete basic activities of daily living (bathing, dressing, eating, toileting) on admission and at discharge, how often and how far you walked in the hospital, your body size, your use of a walking device, your fall risk score, where you are being discharged to, and number of days in the hospital.
4) Provide your telephone number and address to arrange for 3 post-discharge contacts.

Participate on a brief (10 minute) telephone call - one (1) month and six (6) month after you are discharged:

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking (same questions as in the hospital).
2) Answer questions about your movement in different areas of your home and outside your home.
3) Answer questions about whether or not you were readmitted to a hospital.

Participate in an in-person meeting - three (3) months after you are discharged**:**

1) Answer questions about your ability to perform daily life activities, such as bathing, dressing, feeding, and walking.
2) Answer questions about your movement in different areas of your home and outside your home.
3) Do a short test of your walking speed (same one as you did in the hospital).
4) Answer questions about whether or not you were readmitted to a hospital.
5) Participate in a recorded interview (30-60 minutes) about your experience with walking during your hospital stay.

The information and assessments are being collected for research purposes and have no effect on your medical care. This information will not be shared with your doctor or your nurses, will not be used in planning your care, and will not become part of your medical record.

Are there any risks to me?

A breach of confidentiality could result in damage to you or your reputation, but the chances of this happening are very rare. To protect your confidentiality, we will give you a special identification (ID) number that will be used on all data collection forms that we will fill out for this study. Using an ID number reduces the risk that your information could become known to someone who is not involved in conducting this study. Your contact information will be stored in a separate file from your data collection forms. All of your study information, identified by your ID number, will be stored on a password protected server and in a locked file cabinet, located in a locked office in the University of Wisconsin-Madison School of Nursing. Your study records will be kept confidential. Only the research team will have access to your information. You can find out more in the section “Information about Confidentiality and HIPAA Authorization.”

There are four circumstances in which our research team may be required to share specific information about you to someone outside of the research team:

1) If we believe your life is in immediate danger, we will need to call 911 or escort you to an emergency department.

2) If we discover urgent health issues during the interview that could put your life in immediate danger if left unaddressed, we may communicate those specific concerns to your health care provider. We would share your name, contact information, the fact that you are in a research study, and the reason for referral.

3) If we find evidence of child abuse, we are required to report this evidence to Child Protective Services (CPS).

4) If we find evidence of abuse toward an elder or vulnerable adults who cannot make an informed judgment about whether or not to report this abuse (i.e. the person has severe dementia), we are required to report this evidence of abuse to Adult Protective Services (APS). If an elder at risk requests that a research team member report evidence of abuse to APS on his/her behalf, we are required to do so by law whether or not we have witnessed evidence of abuse. Finally, if we find evidence of abuse and the elder makes an informed decision not to report the abuse, we may still be required by state law to report the evidence of abuse to APS if 'other adults are also at risk of serious bodily harm, death, sexual assault, or significant property loss inflicted by the suspected perpetrator.

Are there any benefits to me?
You will not experience any direct benefits from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about how to overcome barriers that limit patients from getting up to walk during their hospital stay.

How much will it cost to participate?
You are not expected to have any costs if you participate in this research study.

Will I be paid to participate?
You will be compensated for your participation at each step - up to $100 total. This will be paid as $25 at discharge, $25 for your participation on the 1 month after discharge phone call, $25 for your participation in the in-person visit 3 months after discharge, and $25 for your participation on the 6 month after discharge phone call. You will be provided the compensation in person at discharge, and in person at the 3-month post discharge visit. Your compensation for the 1- and 6-month post discharge call will be mailed to you.

How long will I be in the study?
You will be in the study during your hospital stay and after discharge. Your participation in the study will end when the 6 month after discharge call is completed.

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you do not want to participate. **Your decision and participation in the study will not affect your treatment at [REDACTED SITE 1] in any way.** If you do not sign this form, you will not be able to participate in the study. You may completely withdraw from the study at any time.

Who oversees this study?
The University of Wisconsin (UW)- Madison (IRB) has approved this study. The IRB is a group of people who review all research studies at UW- Madison to check that they meet federal laws and ethical standards. IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor if you want before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research	Dr. Barbara King Dr. Linsey Steege OR [REDACTED SITE 1] OR [REDACTED SITE 2]	608-263-5319 608-263-5191 OR REDACTED REDACTED
You have questions about your rights as a research subject	[REDACTED SITE 2]	REDACTED
You have questions, problems, concerns, information, input or complaints about this research study	Dr. Barbara King Dr. Linsey Steege OR [REDACTED SITE 1] OR [REDACTED SITE 1] OR [REDACTED SITE 2]	608-263-5319 608-263-5191 OR REDACTED OR REDACTED

Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials, including the U.S. Office for Human Research Protections, responsible for monitoring this study. With appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

A description of this study 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 Web site will include a summary of the results. You can search this website at any time.

Why is access to my health information being requested?

To help answer the research questions, the Research Team will gather and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you do not give this permission, you will not be able to take part in the research study.

What information will be collected and used?
When you are a subject, we will collect health information about you including your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this personal health information (PHI) is protected and cannot be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for [REDACTED SITE 1] to use and disclose your personal health information as described below.

We will be using a study Identification (ID) number to gather and protect patient information for this study. The only personal health information (PHI) collected for this study is your name, address, telephone number, so that we can contact you after you leave the hospital. We will NOT collect other important identifier information including your social security number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?
By signing this Authorization, you allow the research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at [REDACTED SITE 1]) to the following:

Who may have access:	**Purpose:**
The UW and [REDACTED SITE 1] Research Team	To oversee the study and make sure the information is correct
UW IRB and [REDACTED SITE 1] consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies)	To make sure applicable laws are being followed
Organizations that grant accreditation to hospitals and research programs	For [REDACTED SITE 1] and UW- Madison to remain accredited

Will you keep my health information confidential?
We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves [REDACTED SITE 1], we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?
If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?
Access to your personal health information begins as soon as you sign this form. This authorization expires when data collection is complete. Study records will be kept for 7 years and then destroyed.

What if I change my mind?
If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, please contact the study investigators, Barbara King at 608-263-5319 or Linsey Steege, 608-263-5191.

If you withdraw permission for us to use your personal health information:
- You can't continue in the research study.
- We will stop collecting health information from you.
- We will still use and disclose any information that we gathered while you were a subject.
- There will not be any penalty or loss of benefits to which you are otherwise entitled.

Subject name: _____

Telephone Number: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I want to participate in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in a research study record.
- I am not giving up any of my legal rights by signing this form.

Subject signature Date Time

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date Time