IRB Approved: 11/5/2021
Approval Expires: 11/4/2022

OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 8993

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Stopping Elderly Accidents, Deaths, and Injuries (STEADI): Patient Consent

PRINCIPAL INVESTIGATOR: Elizabeth Eckstrom, MD, MPH
Co-INVESTIGATOR: Hiroko Kiyoshi-Teo, PhD, RN

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

PURPOSE:
The purpose of this study is to examine the impact of the falls screening protocol, called Stopping Elderly Accidents, Disability, and Injuries (STEADI) protocol, routinely used at the OHSU Internal Medicine and Geriatrics clinic. The STEADI is considered to be the best fall prevention clinic practice by the Centers for Disease Control and Prevention (CDC). However, limited data exists for long-term impact. We will also evaluate if a research-based, patient-centered communication approach will help STEADI patients to be more motivated in minimizing fall risks.

DURATION:
This is a 1-year study.

PROCEDURES:
The study consists of 2 groups. Group A participants will have 2 study visits and 2 phone calls over the 1-year period. Group B participants will have additional 5 phone calls. When the study staff calls you or meets you, you will be asked a number of questions related to your health, your ability to move around, and fall risks. During the study visits, we will also examine your balance, strength, mobility, and blood pressure. We will record the conversation so that we can accurately capture your responses. You will also keep a calendar that you will mail in to keep track of your mobility and fall events. If you have a fall, we will check in with you to see how you

are doing. We will also review your health records to gather your health information relevant to the study.

RISKS: Although we will make every effort to protect your identity, there is a small risk of loss of confidentiality. We will also make our best effort to be safe and not make you tired during study visits. It is very unlikely, however, you may experience some discomfort during the study procedures.

BENEFITS: You are eligible to receive $15 for each of the study visits and $5 for the study phone calls for your participation. Also, by serving as a participant you are helping us learn how to help patients like you in the future.

ALTERNATIVES: You may choose not to be in this study.

This is a voluntary research study. Even if you decide to join now, you can change your mind later. Please ask the Investigator if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

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Research Consent and Authorization Form

TITLE: Fall prevention in community-based care facilities: An academic-community partnership

PRINCIPAL INVESTIGATOR: **Elizabeth Eckstrom, MD, MPH**

CO-INVESTIGATORS: **Hiroko Kiyoshi-Teo, PhD, RN**

WHO IS PAYING FOR THE STUDY?: National Institute of Nursing Research (expected)

WHO IS PROVIDING SUPPORT FOR THE STUDY?: National Institute of Nursing Research (expected), OHSU Internal Medicine and Geriatrics clinic, OHSU School of Nursing, and OHSU School of Medicine

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?: No.

WHY IS THIS STUDY BEING DONE?:
You are invited to this study because you are patients at OHSU Internal Medicine and Geriatrics clinic, taking an active part in your health, older than 65, and may be interested in minimizing your fall risks. The purpose of this study is to examine the impact of the falls screening protocol, called Stopping Elderly Accidents, Disability, and Injuries (STEADI) protocol, routinely used at the OHSU Internal Medicine and Geriatrics clinic. The STEADI is considered to be the best fall prevention clinic practice by the Centers for Disease Control and Prevention (CDC). However, limited data exists for long-term impact. We will also evaluate if a research-based, patient-centered communication approach, provided mostly by phone, will help STEADI patients to be more motivated to minimize fall risks.

This study involves study visits or phone calls to help reduce your fall risk. This study will enroll about 500 patients.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

The study consists of 2 groups. Group A participants will have 2 study visits and 2 phone calls over the 1-year period. Group B participants will have additional 5 phone calls. When the study staff calls you or meets you, you will be asked a number of questions related to your health, your ability to move around, and fall risks. During the study visits, we will also examine your balance, strength, mobility, and blood pressure. The study visits may take place at OHSU or other designated locations. The questions and examinations at each study visit will be about 2-hour, and each phone call is expected to be about 15-minutes.

You will also keep a calendar that you will mail in to keep track of your mobility and fall events. If you have a fall, we will check in with you during study calls or as a separate call to see how we can help address your concerns and keep you safe.

We will also review your health records to gather your health information relevant to the study.

We will record the conversation so that we can accurately capture your responses.

You have options to be contacted for a follow-up study if interested.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
Although we will make every effort to protect your identity, there is a small risk of loss of confidentiality. We will store your information securely. Your name will not be used to identify the study data. Your name and health information will be linked in one document only and will be accessed only if needed.

We will also make our best effort to be safe and not make you tired during study visits. It is very unlikely, however, you may experience some discomfort during the study procedures.

WHO WILL SEE MY PERSONAL INFORMATION?:
We will take steps to keep your personal information protected, but we cannot guarantee total privacy. We will do our best to keep your information protected by storing it in a secure database.

Once we obtain your personal information, we immediately link with your study ID. We only use your study ID to analyze and present the findings. We may also need to give your information to the Institutional Review Board at OHSU, the funder of the study, the Federal Drug Administration (FDA), or Office of Human Research Protection. These groups oversee research and will protect your data.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?
There are no plans for this study to be used for commercial profit. If there is unforeseen situation occurs, there is no plan to pay you, or for you to have property rights or ownership or financial interest from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?: There will be no cost to you or your insurance company to participate in this study. As a token of appreciation for your time with the study, you will receive $15 for each of the study visits, and $5 for each of the phone calls that you engage in regardless of your activities or engagement with fall prevention. We will also reimburse you for travel costs to the study visits for up to $10. We may request your social security number in order to process any payments for participation.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?:
If you believe you have been injured or harmed as a result of participating in this data collection, contact Dr. Hiroko Kiyoshi-Teo at X (redacted for public sharing purpose).

OHSU and the funder do not offer any financial compensation or payment for the cost of any injury or harm. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

WHERE CAN I GET MORE INFORMATION?:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Hiroko Kiyoshi-Teo at X redacted for public sharing purpose)**.**

This research has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research subjects. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

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

You may also submit a report to the OHSU Integrity Hotline online at www.ohsu.edu/hotline or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

X (redacted for public sharing purpose).

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If in the future you decide you no longer want to participate in this research, we will destroy all your data. However, if your samples are already being used in an ongoing research project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

SIGNATURES:

PARTICIPANT OPTIONS

Please indicate your preference for follow-up study.

( ) Yes, I give my consent to be contacted for the follow-up study.

( ) No, I prefer not to be contacted for the follow-up study.

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date