Form Approved
OMB No. **0920**-XXXX
Exp. Date xx/xx/20xx

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Agreeing to participate indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Listen carefully as this form is read to you.
2. Make sure the study nurse or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Centers for Disease Control and Prevention, NORC at the University of Chicago, and XXXXX.
Consent to be a Research Subject / HIPAA Authorization

Title: Assessing Patient and Provider Adherence to Clinical Fall Prevention Strategies

Study-Supporter: The Centers for Disease Control and Prevention

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study nurse or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not agree to participate unless you have had a chance to ask questions and get answers that make sense to you. By agreeing to participate you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to measure how well a program to help prevent falls in older adults works. The study is designed to test if patients who receive special fall prevention education and treatments are less likely to experience a fall than patients who do not. This study looks specifically at people ages 65 and older. The study also provides the researchers with information about falls that happen and might not be reported to the patient's primary care doctor, whether patients are using fall prevention recommendations at home, and patient diagnoses and prescription medications that may be related to the risk of falling. If the study is successful, it will be able to identify if people who receive the fall prevention services have fewer falls than patients who did not receive the services.

What will I be asked to do?
You are being asked to participate in a study of the reduction of fall risks that result from fall prevention education and treatments described above. People who consent to be a part of the study will be randomly assigned to either to receive the fall prevention services or to receive the usual health care offered by [STUDY SITE NAME]. The study will last for one year starting the day of patient consent, which will include an initial survey at enrollment, and then three follow-up surveys spaced evenly through the year. All people who enroll in the study are being asked to allow study investigators to access their medical information for the purpose of measuring falls treated by [STUDY SITE NAME], and diagnoses and prescription medications related to the risk of falling. None of this information will be released at the individual level outside of the study team and no one outside the study team will be able to identify you. People who participate in the study will receive an invitation letter with instructions for logging in to the web surveys using a secure, custom link. Options for completing the surveys by paper or telephone will also be made available. Each survey will be approximately 10-12 minutes in length, and

will ask questions about any falls you have experienced, visits to medical providers, and changes to your activities, home, or medical care that may be related to fall risk.

Who owns my study information?
If you join this study, you will be donating your study information. Your survey answers and medical record information will be un-linked to your personal identification, and used only for research purposes, without your name attached.

What are the possible risks and discomforts?
There are no serious physical risks to participating in this study. You may refuse to answer any survey question or end your participation in the study at any time, with no impact on the care you usually receive at [STUDY SITE NAME].

Will I benefit directly from the study?
Participants assigned to the falls prevention arm of the study will receive additional fall prevention education and treatments.

Will I be compensated for my time and effort?
All people enrolled in the study will receive $12 in the form of online gift cards (e.g. gift card redeemable on Amazon.com), as a token of appreciation for completing the surveys.

What are my other options?
If you decide not to enter this study, you may receive your usual care at [STUDY SITE NAME].

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

We are required by law to protect your privacy. Names and all other personal identifiers will not be released. The information collected in the surveys and medical records will only be provided in summary reports. The federal law that requires all information we collect to be held in strict confidence is the Privacy Act of 1974, Sections 944(c) and 308(d) of the Public Health Service Act [42 U.S.C. 299c-3(c) and 42 U.S.C. 242m(d)]. If any federal employee, contractor, or agent gives out personally identifying information not authorized by law, he or she is subject to disciplinary action, including fines and criminal charges that may result in jail time.

Storing and Sharing your Information
All information that could identify you will be removed from your survey answers and medical record data, and replaced with a participant ID number. Survey data will be stored by NORC at the University of Chicago in secure servers, and protected to the full extent allowed by law.

The link between your participant ID number and your personally identifying information (name, address, telephone number, email address) will be destroyed within three months of the end of the study. No information that could identify you will be retained by CDC or any other part of the federal government.

Medical Record

If you have been a [HEALTH SYSTEM NAME] patient before, then you already have a health system medical record. If you have never been a [HEALTH SYSTEM NAME], you do not have one. A [HEALTH SYSTEM NAME] will be made for you if a [HEALTH SYSTEM NAME] provider or facility gives you any services or procedures for this study.

[HEALTH SYSTEM NAME] may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your [HEALTH SYSTEM NAME] medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Costs

There are no monetary costs to you for participating in this study.

Withdrawal from the Study

You may refuse to answer any survey question, or end your participation in the study at any time, with no impact on the care you usually receive at [STUDY SITE NAME], and without any other penalty.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use your PHI for the conduct of the research study while the study is ongoing. We will use your PHI to measure past falls and falls which are treated during the study; as well as medical diagnoses and prescription medications before and during the study that may be related to the risk of falling.

Before your study information is used in any analysis or provided to CDC, we will remove identifying information from your PHI. Once we do this, the information will not be subject to the Privacy Rules.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By giving your verbal consent, you give us permission to use and share your PHI as described in this document. You do not have to give us your verbal consent to authorize the use and disclosure of your PHI. If you do not give us your verbal consent, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you give your verbal consent, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

[contact info]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Contact Information

Contact NAME at xxx-xxx-xxxx

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the NORC Institutional Review Board at xxx-xxx-xxxx or xxx-xxx-xxxx or irb@norc.org:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

If you are a patient receiving care from [HEALTH SYSTEM NAME] and have a question about your rights, you may contact XXX.

Consent and Authorization

Do you have any questions about the study?
Do you agree to participate in this study?

_____

Name of Subject

☐

If box is checked, subject gave verbal consent to participate

_____

(18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**