Washington University in St. Louis

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IRB ID #: 201710186
APPROVAL DATE: 01/02/24
RELEASED DATE: 01/02/24
EXPIRATION DATE: 12/31/24

INFORMED CONSENT DOCUMENT

Project Title: Aging with Long Term Physical Disabilities

Principal Investigator: Susan Stark, PhD, OTR/L

Research Team Contact: Emily Somerville, OTD, OTR/L, (314) 273-4117

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

This is a research study conducted by Susan Stark, PhD, OTR/L having to do with improving participation in home and community activities for individuals aging with a long-term physical disability. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend about 8 months in the study. All visits will occur in your home. During your time in the study, you will be asked to complete about 6 visits in your home over a 6-month period. During the visits, we will ask you questions about barriers to your participation in activities in the home and community. After the first visit, participants will be randomly assigned to a group: the home modification group will receive a home modification intervention to improve participation and the life history group will be asked questions about their experiences aging with a disability over 4 visits. After the 6-month follow-up visit, the life history group will also be offered the home modification intervention. We will contact you monthly to find out if you have had any falls during the 6-month follow-up. The main risk to you if you participate is that you may become tired during one of the visits.

You may benefit from volunteering because you will receive a home modification intervention with a registered and licensed occupational therapist designed to improve

your ability to participate in activities in your home and community. By volunteering you may help someone else in the future. There is no cost to you and you will be paid up to $30 for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are an individual aging with a long-term physical disability.

The purpose of this research study is to determine the feasibility of a home modification intervention to improve the daily lives of individuals aging with a long-term physical disability living in the community.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participant in the study, all visits will take place in your own home and will last approximately 75 minutes. First you will complete a home assessment with an occupational therapist (OT) to identify barriers to participation in activities in your home and community. During the visits, you will be asked questions about your health and participation in activities in the home and community. You will also demonstrate how you do different activities in your home. Following the initial visit, all participants will be randomly placed into one of two groups:

Home Modifications: The home modification group will receive 4 additional home visits lasting about over an 8-week period. During the visits, the OT will help you address barriers in your environment to completing daily activities in your home and community. The OT will help you obtain modifications and train you and your caregiver (if applicable) on how to use the modifications.

Life history: The life history group will receive 4 additional home visits over an 8-week period. During these visits you will be asked to share experiences about aging with a disability.

Follow-up for all participants: After the initial study visits, participants will complete a survey over the phone or e-mail on a monthly basis to report any falls they may experience. At 6-months, a final home assessment lasting will occur. After the final

assessment, individuals in the life history group will be offered the home modification intervention (4 home visits over 8 weeks).

If we are unable to contact you, we will try via phone or e-mail at least 5 times. If we are still unable to reach you, we will send you a letter in the mail.

Will you save my research information to use in future research studies?

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Audio/Video Recording or Photographs

One aspect of this study involves taking audio recordings and/or photographs of your home to document barriers in your environment and any modifications that are made. No photographs of people will be taken, or any that will let others recognize your home. Photographs will be stored electronically in a double locked electronic database. Only the principal investigator and members of the study team will have access to the photographs and audio recording. Photographs will be kept as a part of the electronic record.

I give you permission to take audio recordings and photographs of my home during this study.

_____ Yes _____ No
Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 700 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 8 to 10 months. During this time, all participants will receive an initial and 6-month home assessment. The home modification intervention includes up to 4 visits and the life history group will receive an additional 4 visits. All visits will last approximately 75 minutes and occur over the phone and/or in your home.

WHAT ARE THE RISKS OF THIS STUDY?

Likely: In-home evaluations and assessments of barriers may cause you to feel fatigue or aggravation.
Less likely: Some questions may touch on emotionally-sensitive issues that could cause you anxiety, embarrassment, or other forms of emotional stress.
Testing and assessments will be stopped if you develop fatigue, agitation, or emotional distress. You can take a break or you can finish the questions at another time.
Rare: In rare instances, the home evaluation protocol could result in your falling. We will minimize risk by having a licensed and trained interventionist available to monitor safety during the home, and gait belts will be used at all times during the home visits.

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. The risks to this study are minimal, you may become tired during the home visits or uncomfortable answering questions.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled "How will you keep my information confidential?" for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. All participants will receive a home evaluation with an occupational therapist and assistance reducing barriers to improve daily activities.

However, we hope that, in the future, other people might benefit from this study because we will better understand the needs of people aging with long-term physical disabilities to improve participation in daily activities.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. We ask that you provide your social

security number (SSN) in order for us to pay you. If you do not wish to provide your social security number (SSN), you may choose to participate without providing it. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. You will receive a reloadable debit card and will be paid $5 on the card each month that you report whether or not you have had a fall during the 6-month follow-up period.

WHO IS FUNDING THIS STUDY?

The National Institute on Disability, Independent Living, and Rehabilitation Research is funding this research study. This means that the Washington University is receiving payments from The National Institute on Disability, Independent Living, and Rehabilitation Research to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from The National Institute on Disability, Independent Living, and Rehabilitation Research for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institute on Disability, Independent Living, and Rehabilitation Research
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign your study data a study identification number and all data collected will be labeled with that number. All data will be kept under double-lock protection. All hard copy forms that contain personal identifiers (e.g., name, address, phone numbers) will be stored in a separate locked file drawer under double-lock protection. To guard against unauthorized data access, all shared-use computer systems at Washington University School of Medicine are protected with passwords. Only individuals with a particular "need to know" status are given access, and system privileges are carefully restricted. All personal computers to be used in the Administrative Unit are located within a secure area, and the system is locked when not in use.

In order to complete the automated phone calls, your first name and phone number will be shared with Twilio, an online communication software designed to make automated phone call surveys. To complete the call, Twilio will access your first name and phone number. Your survey responses will be temporarily stored by Twilio, transferred into Washington University's secure databases, and deleted from Twilio as soon as possible.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study. Withdrawal from the study will not affect any care that you are receiving outside of the study.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen because it may be in your best interest to no longer participate in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Emily Somerville, 314-273-4117.** If you feel that you have been harmed in any way by your participation in this study, please contact **Susan Stark, 314-273-4113.**

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/31/24.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)