UNIVERSITY OF WASHINGTON CONSENT FORM

Aging with Pride: Innovations in Dementia Empowerment and Action (IDEA)

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Co-Principal Investigator: Karen I. Fredriksen-Goldsen, Professor, UW School of Social Work, [redacted]

Project Director: Hyun-Jun Kim, Research Scientist, UW School of Social Work, [redacted]

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form after it is signed for your records.

PURPOSE OF THE STUDY

The purpose of this research study is to understand challenges and barriers experienced by adults with memory loss or other dementia-related symptoms and their care partners and examine ways to improve their health and quality of life, focusing on the role of exercise and caregiving quality.

STUDY PROCEDURES

If you decide to be in the study, you will be randomly assigned as a pair to one of two intervention programs. In both programs, the two of you will meet with a coach for nine 1-hour sessions over six weeks to learn new ways to help prevent cognitive and physical decline. The sessions are twice a week for the first three weeks then once a week for the next three weeks, Sessions will take place either in your home or at another locations agreed upon with your coach or using a video conferencing platform such as Zoom, Skype or FaceTime. Sessions will be audio-recorded and rated by experts to monitor content and the coach's delivery of program components, problem-solving abilities, and general skills. The coach will give you both exercises to do together every day, such as repeatedly standing up from a chair, leaning and reaching from sitting or standing position, stepping over objects while walking, or walking on toes or heels. The coach will demonstrate each exercise and make sure you are doing it correctly. The coach will introduce the exercises in stages over the nine sessions. In addition, your coach will work with you to identify and modify behavioral patterns in the person with memory loss that can impair day-to-day function, adversely affect your interactions, and interfere with exercise participation. After these nine sessions, the coach will contact you by phone once a month for the next four months for a brief review of the program.

A research interviewer from the University of Washington will interview you 5 times by phone over 13 months. The interview will take about 40 minutes - 1 hour and it will be the same each time. The interview questions will be about the person with memory loss and yourself. We will ask about the

health, moods, feelings, and activities of the person with memory loss. We will ask about your caregiving effort, health, and activities. For example, we might ask, "In the past week, how often have you found that you could not cope with all the things that you had to do?"

RISKS, STRESS, OR DISCOMFORT

You may feel some discomfort when talking about providing assistance or about the person with memory loss. You may call the coach if you feel distressed. You may refuse to answer any question you do not want to answer.

There are risks to the exercise portion of this study, as can occur with any exercise program. Most injuries affect muscles, bones and joints. They may include aggravation of existing arthritis; injury to a joint such as torn cartilage; bursitis or tendonitis; or torn muscles. Most of these injuries cause temporary health problems, though they may cause chronic health problems. The risks of endurance training (walking) are fatigue, muscle soreness, and possible joint or bone injury. These risks are reduced by warm-up exercises and cool-down periods, which are described in the exercise instructions. Following instructions provided by the coach will also reduce the possibility of injury.

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve the potential for a breach in confidentiality.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You may choose not to take part in this study. There are other programs for older adults in your area. Your doctor or coach could tell you about programs in your community.

BENEFITS OF THE STUDY

You may benefit from this study by learning how to handle situations that occur with older adults having memory problems and by learning some simple, easy-to-follow exercises that have improved health in other older adults with and without memory problems. The results of this study could increase our understanding of how to help other people experiencing what you are experiencing.

SOURCE OF FUNDING

This study (PIs: Dr. Fredriksen-Goldsen and Dr. Teri) is funded by National Institutes of Health and National Institute on Aging.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

We have a Certificate of Confidentiality from the federal National Institutes of Health (NIH). This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- your local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when NIH funding for this study ends. Currently this is 5/31/2022. Any data collected after expiration is <u>not</u> protected as described above. Data collected prior to expiration will continue to be protected.

Data collected from you are kept strictly confidential. Your information will be assigned an identification number that is unique to this study. Only the Principal Investigator and authorized research staff will be able to access your name, address, phone number, email address, and link to the identification number. The only exception would be incidents of abuse of a dependent adult or minor child and risks of imminent harm to others or to yourself that you might report to the interviewer. If risk to yourself or others is revealed during the session, the project staff must report that to the authorities as required by law.

Recordings of sessions will be sent to UW researchers who will view and listen to the recordings. The link between your identifying information and the research data will be destroyed after the records retention period required by state and/or federal law (6 years after the close of the study). Government or University staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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 website will include a summary of the results. You can search this website at any time.

RESEARCH-RELATED INJURY

If you think you or the person to whom you provide care have an injury related to this study, contact your coach right away. The coach may refer you for treatment.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

For additional information about giving consent or your rights as a participant in this study, contact the University of Washington Institutional Review Board Office at 206-543-0098.

You will receive $25 as a pair as reimbursement for your time for each of 5 phone interviews.

_____	_____	_____
Printed name of study staff obtaining consent	Signature	Date

Subject's statement:
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the University of Washington Human Subjects Division at (206) 543-0098. I will receive a copy of this signed consent form.

_____	_____	_____
Printed name of study subject	Signature	Date

Copies to: Researcher, Subject