Consent Form – Senior Companion

Title of Research Study: Utilizing Senior Companions to Enhance Dementia Care Services and Supports: R61 Phase

Investigator Team Contact Information: Joseph Gaugler, PhD.

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Joseph Gaugler, Ph.D. Investigator Departmental Affiliation: University of Minnesota – School of Public Health; Department of Health Policy and Management Phone Number: 612-626-2485 Email Address: gaug0015@umn.edu	Study Staff: Katie Louwagie, DNP Position: Research Coordinator Phone Number: 612-626-4776 Email Address: wocke007@umn.edu

Supported By: This research is supported by the National Institute on Aging.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you have requested to volunteer through Lutheran Social Service as a Senior Companion to either a caregiver who is caring for someone with memory concerns, or someone with Alzheimer's disease or related dementia.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

A lot of the time, it is hard to find the right kinds of services and support for people with memory concerns and their family members. We at the University of Minnesota are collaborating with the Lutheran Social Service of Minnesota to provide additional training on Alzheimer's disease, dementia, and memory loss to Senior Companions. If successful, we hope this project can serve as a model for

other communities helping people with memory concerns.

How long will the research last?

We expect that you will participate in this study for up to 16 months. This will be broken down into a training period (about 12 hours of CARES® and 4 hours of PorchLight Project training) and 3 months of working with family caregivers and/or persons with memory concerns. You will work with each caregiver and/or person with memory concerns for 3 months at a time.

What will I need to do to participate?

If you sign this consent form, you will be enrolled as a volunteer Senior Companion in this research study. At this point, we will ask you to complete a survey that will take about 10 minutes. Then, you will be asked to complete CARES® training online (about 12 hours), complete an online credentialing exam to become a "CARES® Memory Support Specialist" (exam can be re-taken if needed), and attend additional training provided by University of Minnesota research staff either in-person, online, or via telephone (about 4 hours). Once you have completed this training, you will go out into the field (for in-person or telephone visits with the caregiver and/or person with memory concerns who you are helping on a weekly basis), and record your notes and thoughts as a journal entry. During your time in the study, we will also ask you to partake in monthly check-ins as able (via phone and/or in person) to review specific cases, discuss challenges and potential solutions, and receive addition education as needed. After 3 months, we will conduct a 30-45 minute recorded interview with you to learn about what did and did not work**.**

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

Working with caregivers and/or persons with memory concerns could be difficult at times, as providing help to someone with memory concerns and their family members can be stressful, and those with memory loss can sometimes exhibit unpredictable behavior. There is always a possibility that we could lose your information or your privacy is breached because of a computer security problem. Please be assured that we take serval measures to protect your information, and by extension, your privacy. Should a breach occur, we would be in contact with you as immediately as possible.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include feeling better about the care the person(s) you are helping receives.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 45 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

- After the research coordinator or research assistant finishes going over this form with you, she will send you a survey to complete. It should take about 10 minutes to finish.
- After completion of the baseline survey, we will provide you with the necessary training materials.
- You will be required to finish the CARES® and PorchLight Project trainings by the expected dates of completion.
- Once your training is complete, you will be working with a caregiver and/or person with memory concerns over a 3-month period. This will include meetings, home visits, utilization of a set of guided questions, as well as journaling sessions and monthly reviews of specific cases, discussion of challenges and potential solutions, and provision of additional education as needed.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to receive the Senior Companion program, any present or future medical care, your relationship with the University of Minnesota, or your present or future employment.

We will continue to use the data you provided us up to the time you decide to withdraw from the study. We will not ask you for permission for any additional interaction or collection of private identifiable information.

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improvements in both your well-being and the person you care for, as well as the person you care for receiving better services for their memory concerns.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance, as well as the U.S Department of Health and Human Services as this study is funded by the National Institute on Aging.

We will not ask you about vulnerable adult abuse, but if you tell us about vulnerable adult abuse or neglect, we may be required or permitted by law or policy to report to authorities.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web-site will include a summary of the results. You can search this web-site at any time.

Data Collected
All data collected as part of this study will be stored in Dr. Gaugler's research office in D351 Mayo Building at the University of Minnesota in locked file cabinets. All data collected on-line or entered will be stored on a secure Academic Health Center-Information Systems data server.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research- participants/questions-concerns.

You are encouraged to contact the HRPP if:

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

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

You will not be compensated by the University of Minnesota for volunteering to be a Senior Companion in this research study.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Joseph E. Gaugler, PhD.
_____	_____	I accept the use of unencrypted email as a way to communicate with the research team members. I understand that unencrypted email communication is not secure and can be intercepted

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Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Your Signature Date

_____

Your Printed Name

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent