Consent Form - Client

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 or 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 a doctor gave you a diagnosis of Alzheimer's disease or a related dementia, or based on some of the initial questions that we asked you, you have some memory concerns.

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 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 be in this research study for 4 months. We will ask you to complete 45-60 minute surveys, as well as an interview at the end of the study that should take another 45 minutes or so.

What will I need to do to participate?

You will be asked to complete an initial, 1-month, and 3-month survey, and also complete a more open-ended, recorded interview of the telephone after the 3-month survey. During this time, your Senior Companion will visit and help you.

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?

Answering some of the questions might make you sad or upset, as we ask about how well you are doing these days in terms of your memory and health. 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 you receive.

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, you will be asked to complete an initial survey (either in person or via phone/mail). It should take about 45-60 minutes to finish.
- After completion of the baseline survey, the Senior Companion will work with you to provide referral to services in the community, help you navigate visits with doctors or healthcare providers if possible, and provide guidance, support and education. The Senior Companion will do this over the phone or in person as you need it.
- At 1- and 3- months, we will ask you to complete a telephone/mailed survey about your

health, well-being, and answer questions to help us understand how well the Senior Companion program is or is not working for you. This should take you about 30 minutes or so to complete.

- After we receive your 3-month survey, we will set up a time with you to complete a telephone interview (about 30 minutes) to share with us why the Senior Companion program was or was not useful to you. Please note, we will record this interview if you agree to it.

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 your well-being and receiving better services for your 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 private information 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?

If you agree to take part in this research study, we will pay you $25 after completing the baseline, 1-month, and 3-months surveys as well as the 3-month interview for a total of $100 if you complete all four assessments.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be

given your name and date of birth. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

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.

Consent Form - Client

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

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Consent Form - Client

Your signature documents your permission for the named participant to take part in this research.

_____

Printed Name of Participant

_____ _____

Signature of Legally Authorized Representative Date

_____ _____

Printed Name of Legally Authorized Representative Date

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Printed Name of Person Obtaining Consent Date