OREGON HEALTH & SCIENCE UNIVERSITY

IRB#: 17123

Research Consent Summary

You are being asked to join a research study. You do not have to join the study. Even if you decide to join now, you can change your mind later.

1. The purpose of this study is to create a nationwide home based system for research that will determine how we can optimally enhance the health and wellbeing of older adults. This is to be accomplished by participants using simple existing technologies such as medication minding pill boxes and wristwatches that assess mobility and sleep to ideally detect early health and activity changes occurring in daily life. The long-term goal is to maintain health and independence with aging with a nationwide network of participants informing researchers as to how to best achieve this goal.
2. We want to learn
    a. The best ways to deploy the home-based technologies that will detect meaningful health changes in older adults who may be at risk of unrecognized medical needs or loss of independence and;
    b. If recruiting participants and installing this technology into their homes across the country will improve the research that helps us to understand how to support seniors to maintain their health and independence.
3. Funding for this project is provided by both the National Institutes of Health (NIH National Institute on Aging, National Cancer Institute, National Institute of Biomedical Imaging and Bioengineering, National Institute of Neurological Disorders and Stroke, National Institute of Nursing Research, Office of Behavioral and Social Sciences Research, and National Center for Advancing Translational Sciences) and the Department of Veterans Affairs.
4. Everyone who joins the study will complete an initial 2 hour assessment visit followed by an installation of study equipment in your home (up to 3 hours). Every year you will complete an additional 2 hours of clinical and memory testing, as well as having occasional visits to maintain the study equipment. The study will last for approximately 3 years. You will also complete a weekly online behavior & health questionnaire.
5. There is a risk to participants with pacemakers when they use the scale, so they are advised to wear socks/shoes as a precaution. There is a small risk of breach of confidentiality.
6. Information collected during the study may be saved for future research.

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Research Consent and Authorization Form

TITLE: ORCATECH Collaborative Aging (In Place) Research Using Technology (CART)

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David Lowenstein, PhD (305) 355-7016

FUNDED BY: National Institutes of Health
National Institute on Aging (NIA)
National Cancer Institute (NCI)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
Office of Behavioral and Social Sciences Research (OBSSR)
National Center for Advancing Translational Sciences (NCATS)
Department of Veterans Affairs

PURPOSE:
You have been invited to participate in this research study because you are 62 years of age or older, live alone or with a partner, and are living independently or with minimal assistance.

The purpose of this study is to create a nation-wide home based system for research that will determine how we can improve the health and wellbeing of older adults. This is to be accomplished by participants using simple existing technologies such as medication minding pill boxes and wristwatches that assess mobility and sleep to ideally detect early health and activity changes occurring in daily life. The long-term goal is to maintain health and independence with aging with a nationwide network of participants informing researchers how to best achieve this goal.

This study will last 3 years. At the end of the 3 years, you may be asked if you would like to join a follow-on study.

The information collected as part of this study will become part of a data bank, also called a data repository. This information will be stored indefinitely and may be used and disclosed in the future for research.

Up to 800 participants will be enrolled in this study, with up to 200 recruited by the OHSU study site and up to 200 recruited by the University of Miami and Cornell Weill Medical sites.

PROCEDURES:
There are two parts to this study: clinical assessments and in-home monitoring.

Clinical assessments
If you agree to participate in this research project, you will be asked to have a baseline study visit with research staff which will include the consent process, filling out demographic and health information, and completing a number of assessments with research staff. Each year, you will have a follow-up assessment visit and will update demographic and health information at that time. Please note that these assessments are being conducted as part of a research study and are not for use as part of your clinical care. All information will remain confidential, as stated in the CONFIDENTIALITY section. If you have already completed some or all of these tests through another study within the appropriate timeframe, you will not need to complete the assessments a second time. Further description of these assessments and the time required can be found below in the Study Visits section.

At your baseline home visit, you will have your photograph taken. The photograph will be stored in the ORCATECH Management Console with your information, available only to study staff to provide them a visual confirmation that when they go to visit a participant, they are speaking to the right person. We will use the photograph only for research purposes; it will be included as part of your entry in our research database. It will not be used for publicity purposes.

During your visit, we may ask to record some of your responses to the tests. The voice recordings will be stored indefinitely in password-protected computers. Your name or other protected information will be not used. Instead, we will identify you by assigning a unique identifier to your voice recordings.

In Home Monitoring
We will install in-home sensors to help us monitor your physical and computer activity patterns and how those patterns relate to changes in your medication and cognition. We will put this sensor system in your home to collect information about your computer use and activity throughout your home. The sensor system requires an Internet connection – typically via broadband service. In order to participate in this study, you will need to provide your own broadband service – typically $40 – 60 per month. Your household will receive a monthly stipend of $49 for the duration of the study to help offset the cost of Internet service.

To begin, the study staff will set up a time for the system to be installed in your home, which will take up to three hours depending on the size of your home. The sensor system will be taken out of your home at the end of this study or when you wish to stop taking part. This will take about 30 minutes and will be done at a time that is convenient for you.

In-home Assessment System Components:
Components required for study participation

- A small computer will be used to collect and send us the sensor information. This device will be placed in your home in a location that is out of sight.
- You will be asked to complete a weekly online behavior and health questionnaire that typically takes less than 5 minutes to complete. You may receive a phone call to follow-up on your responses if information you provide is not complete or appears inaccurate.

- Sensors will be placed on exit or entry doors to tell us when they are open or c
- Motion sensors will be placed in each room of your home, including your bedroom, bathroom, hallway, kitchen, and other living areas. These sensors do not record any sound or pictures, but simply tell us when a person passes in front of them.

Optional components

- You will be asked to weigh yourself on a scale daily which will communicate with our system.
- You will be asked to use a pillbox device for your medication. This device allows us to look at your medication taking habits.
- If you have a car that you drive that is a 1996 or newer model, we will install a sensor in the car that will track your driving habits during the duration of the study.
- You will be asked to wear a watch-like device daily during the study. This device helps us understand your physical activity levels both in and out of the home.
- You will be asked to have software installed on your computer which monitors your basic computer use. This software will be removed at the end of the study.
- You will be asked to have a sensor placed under your mattress (NEW device in 2019). This device will enhance and validate the sleep data which is already being collected by the watch-like device and the motion sensors. This device collects heart and breathing rates, heart rate variability, and movement activity (such as tossing and turning).

All sensors will be attached with removable picture hanging strips. There is a small risk that some paint will come off the wall when the sensors are removed. If there is damage, we will do our best to repair it.

Please note that the sensor system is *not* a security system. It will not detect break-ins, falls or emergencies and will not be able to notify anyone in the event of an emergency.

The system detects activity in your home and wirelessly sends the information to the research project staff. All data is kept strictly private (as described below in the **CONFIDENTIALITY** section).

During the project, you may be asked to allow research staff to come into to your home to test, replace or re-install parts of the sensor system. We will try to make as few visits as possible. If there is more than one person who lives in your home, each person will sign a consent form to participate in this study. At the end of the study, we will set up a time to remove the system.

In the future, your data may be given to researchers and the funder of this project for other research studies. The data will be labeled as described in the **CONFIDENTIALITY** section.

Study Visit Flow for Participant

	Baseline Visit	Platform Installation Visit	Month 12	Month 24	Month 36	Platform Removal
Consent & Authorization Forms	X					
Demographics Form	X					
CART SES & Employment Form	X		X	X	X	
Physical Health Assessments						
Physical Assessment Form	X		X	X	X	
Mobility Form	X		X	X	X	
Subject Health History	X		X	X	X	
Subject Medications	X		X	X	X	
Clinician Assessed Medical Conditions (OHSU & Portland VA only)	X		X	X	X	
Modified Cumulative Illness Rating Scale (CIRS) (OHSU & Portland VA only)	X		X	X	X	
OARS ADL/IADL	X		X	X	X	

Physical Activity Scale for the Elderly (PASE)	ONLINE		ONLINE	ONLINE	ONLINE	
Pittsburg Sleep Quality Index	ONLINE		ONLINE	ONLINE	ONLINE	
Habit Assessments						
CART Habits Form	X		X	X	X	
Cognitive & Behavioral Assessments						
CART Cognitive Status Form	X		X	X	X	
MoCA	X		X	X	X	
Craft Story 21 (Immediate)	X		X	X	X	
Benson Complex Figure Copy (Immediate)	X		X	X	X	
Number Span Forward (WAIS-R)	X		X	X	X	
Number Span Backward (WAIS-R)	X		X	X	X	
Category Fluency (Animals)	X		X	X	X	
Category Fluency (Vegetables)	X		X	X	X	
Trail Making Test, Part A & B	X		X	X	X	
Craft Story 21 (Delayed)	X		X	X	X	
Benson Complex Figure Recall	X		X	X	X	
Multilingual Naming Test (MINT)	X		X	X	X	
Letter Fluency (F, L)	X		X	X	X	
Generalized Anxiety Disorder 7-item (GAD-7)	X		X	X	X	
UCLA Loneliness Scale	ONLINE		ONLINE	ONLINE	ONLINE	
Lubben Social Network Scale	ONLINE		ONLINE	ONLINE	ONLINE	
Geriatric Depression Scale (GDS)	X		X	X	X	
Care & Support Assessments						
Zarit Burden Interview (Couples only)	ONLINE		ONLINE	ONLINE	ONLINE	
Quality of Life						
RAND 36-Item Health Survey (SF-36)	ONLINE		ONLINE	ONLINE	ONLINE	
Technology Related Visits and Assessments						
ORCATECH Technology Use Survey	ONLINE		ONLINE	ONLINE	ONLINE	
Device Usability Survey			ONLINE	ONLINE	ONLINE	
CART Participant Experience Survey			ONLINE	ONLINE	ONLINE	
CART Platform Installation		X				
CART Platform Maintenance/Upgrades		As needed during the CART project				
CART Platform Removal						X
Online Weekly Questionnaire		Weekly for duration of CART project				
TIME PER VISIT	**2-3 Hours**	**1-3 Hours**	**1-2 Hours**	**1-2 Hours**	**1-2 Hours**	**.5-1 Hour**

RISKS AND DISCOMFORTS:

There is a potential risk to anyone with a pacemaker who uses the scale provided by the study. The Nokia Body Cardio circulates a small electrical signal in your body to perform some of its measurements such as fat mass, which may interfere with a pacemaker or other medical device. If you have a pacemaker you are advised to wear shoes/socks while stepping on the scale. Study staff will also disable the functionality of the scale that can interfere with a pacemaker if you have one. If you get a pacemaker during the course of the study, please alert your study team so they can disable the functionality of the scale that can interfere with a pacemaker.

There is a minor risk that sensors installed in your home (described in more detail abo surfaces and potentially cause injury or damage. These sensors weigh less than 0.25 pounds and are about the size of a man's thumb. We will do our best to repair any damage caused by the sensors.

There is always a risk of a loss of confidentiality. All study personnel will receive training about HIPAA and the responsibilities that accompany the conduct of research. The repository housing data from this protocol (OHSU eIRB#17189) contains policy that defines procedures for protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines, for accessing limited data sets, and for protecting the integrity of original work contributed to the database.

By storing or sending personal information on your computer there is some risk that it may be accessed by anyone with physical or remote access to your computer. If your computer is lost or stolen, the person in possession of the computer may have access to information you would choose to keep confidential. Because of this, you should always exercise caution in what information you put on the computer. The software that we install on your computer encrypts (or scrambles) the data it transmits so that it cannot be accessed by people other than those granted access by this document.

Information that identifies you will be used in this study and shared with the study sponsors and research staff. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft.

In this study, you will be asked questions about your quality of life at the yearly assessments. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

The weekly health survey will ask you about your mood and health. These questions are part of the research study and are not meant to detect urgent medical needs. If you feel you need urgent medical attention during the course of this study, you should contact your primary care provider or call 911. If you are having thoughts of suicide, you should call the National Suicide Prevention Hotline and/or the Veterans Crisis Line, which will be provided on the weekly health survey. If the study team does become aware of a potentially urgent medical issue during the course of the study, we will refer you to your primary care provider and the National Suicide Prevention Hotline and/or the Veterans Crisis Line, if indicated.

BENEFITS:
You will receive monetary compensation of $49 per household that can be used towards maintaining internet connection. You may find you feel less isolated due to visits from study staff. There is otherwise no direct benefit associated with participation in this study, although seniors may benefit from the information gained from this study in the future.

ALTERNATIVES:
You may choose not to be in this study.

CONFIDENTIALITY:
We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. You are responsible for the physical security of the study equipment in your home. If someone not involved in this research removes the hub computer from your home, they would potentially be able to access the sensor data from your home.

Some study tests are completed in an encrypted database called REDCap. The REDCap database is a password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health and Science University (OHSU). A user profile based on your study ID number will be created for you, which will not contain your name or other identifying information. The database will collect your responses to questions, but will not contain any identifying information about you. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

Some study surveys are completed using cloud software called Qualtrics. Qualtrics is password protected.

Your full name, study ID number and email address will be stored on the Qualtrics server to send you study surveys and to enable CART study staff to manage survey administration. The Qualtrics server will collect your responses to questions. By signing this informed consent, you give permission for this data to be stored on the Qualtrics servers and maintained by CART study staff, who will be responsible for maintaining the security and confidentiality of the transferred data.

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository to conduct future research.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funders of this study, and the funder's representatives
- The National Institutes of Health
- The National Alzheimer's Coordinating Center (NACC)
- The Office for Human Research Protections, a federal agency that oversees research involving humans

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission. Information may be sent to the National Alzheimer's Coordinating Center (NACC) funded by the National Institute on Aging. The only piece of identifying information that will be shared is your age. Your identity will not be disclosed unless you give separate and specific consent for it.

To help us protect your privacy, this study and the National Alzheimer's Coordinating Center – NACC have obtained a Certificates of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. However, if we learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, we will report that to the proper authorities.

When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

Data from this study may be shared with other investigators for future research studies. All identifying information about you, except your age, will be removed before the information is released to any other investigators.

We may continue to use and disclose your information as described above indefinitely.

COMMERCIAL DEVELOPMENT:
Information including any photographs, videotapes, or audiotapes about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could be patented or licensed to a company or helping a company to do research. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

COSTS:
Your household will receive a monthly stipend of $49 for the duration of the study to help offset the cost of internet service. You may receive payment via a debit card or a gift card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and Frequently Asked Questions (FAQ) sheet.

LIABILITY:
If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Dr. Kaye at (503) 494-6695, the OHSU study team at (503) 418-9328, or the University of Miami study team at (305) 355-9062.

You have not waived your legal rights by signing this form. If you are harmed by the study procedures, you will be treated. Oregon Health & Science University does not offer to pay for the cost of the treatment. Any claim you make against Oregon Health & Science University may be limited by the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

PARTICIPATION:
If you have any questions, concerns, or complaints regarding this study now or in the future, contact Dr. Kaye at (503) 494-6695, the OHSU study team at (503) 418-9328, or the University of Miami study team at (305) 355-9080.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

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

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study.

Because this is an observational study, we will not give you any results of our data. However, if we find information that is relevant to your health care, we will notify you and suggest that you discuss this information with your primary care provider or other trusted clinician.

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. If you choose not to join this study, or if you withdraw early from the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study.

If you no longer want your health information to be used and disclosed as described in send a written request or email stating that you are revoking your authorization to:

Mail to:
Dr. Jeffrey Kaye
Oregon Health & Science University CR-131
3181 SW Sam Jackson Park Rd Portland, OR
97239

Email:
kaye@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you choose to withdraw, we may ask you to provide some information about why you chose to withdraw. We will also need to visit your home to uninstall any technology we may have installed.

If in the future you decide you no longer want to participate in this research, we will stop collecting information from you and any devices that send data to us. We will remove your name and any other identifiers from your information, but material already collected will not be destroyed and we will continue to use it for research.

You may be removed from the study without your consent for the following reasons:

- Not meeting the inclusion criteria for the study.
- Meeting the exclusion criteria for the study.
- Not following the instructions given to you by the study team.
- The study is discontinued for administrative reasons.
- Should you get a health condition that could affect your participation.
- Investigator may decide that it is not in your best interest.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

University of Miami Participants ONLY:
In our study we are interested in learning about how older adults use computers and their attitudes toward using this technology. If you would like to be in these kinds of research studies, we ask you to initial below so we can contact you in the future for similar studies. You will always have the right not to be in any future studies.

_____
Initials

SIGNATURES:

Your signature below indicates that you have read this entire form and that you agree to be in this study.

We will give you a copy of this signed form.

Subject Printed Name	Subject Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date