Title

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

Investigators

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Specific Aims/Purpose

Regardless of age and throughout life high value is placed on being independent. Unfortunately, as one ages, the ability to remain independent and in particular to age in place (AiP) or pursue one's life of choice becomes a risk laden venture, especially for those age 85+, a large and rapidly growing portion of the population. After age 65, 70% of Americans will need some long-term care services (adult day services, home care, assisted living, nursing home) to maintain independence during the remainder of their lives [1]. The amount spent on these services in the United States (in 2012) was
$219.9 billion [2] not including care provided by family or friends on an unpaid basis (often called "informal care"). Approximately 40 million Americans (mostly women; 66%) provided unpaid support to an adult at an estimated economic value of $375 billion [3]. Considering the growth of the aging population and that even just one major chronic condition such as Alzheimer's disease is projected to require care costs of over $1 trillion dollars by 2050, the status quo is not tenable [4].

Key to addressing these challenges is the ability to provide more effective means of facilitating independence and health for as long as possible. During the past decade, a profusion of potential technologies and protocols have been introduced and developed to address this need. These technologies take advantage of important developments in sensing and pervasive computing, wearable technologies, mobile and wireless communications, health information technology systems and "big data" analytics. Notwithstanding this abundance of opportunities, the true value of these approaches has yet to be fully evaluated, developed or implemented. Despite indications of high promise [5-7], the evidence base remains incomplete.

The Collaborative Aging (in Place) Research Using Technology (CART) initiative establishes the means to build the needed evidence now and well into the future. Our CART project fully aligns with the FOA call for the creation of a sustainable infrastructure for the AiP research community, ultimately fostering efficient recruitment of research participants, identification and qualification of useful and usable equipment and software, the conduct of research, and collection and pooling of data using a rapid and reliable data management system. Importantly, the proposed CART program will develop and validate its activities using a unique research team with over a decade of experience in the domain specific to aging and pervasive computing research deployed in the homes of hundreds of older adults. **To achieve our goals the Overall Aims of the CART project, which are reflected by the aims of each site, including the VA, are to:**

1. Establish and implement the administration and operational infrastructure for CART. This includes providing guidelines and protocols for the basic governance, operational, and policy structures (privacy, security, IP, data sharing, etc.) needed to develop and sustain an infrastructure to enhance aging in place research using technology, as well as establishing and coordinating requirements, standards, specifications, and resources for this research.

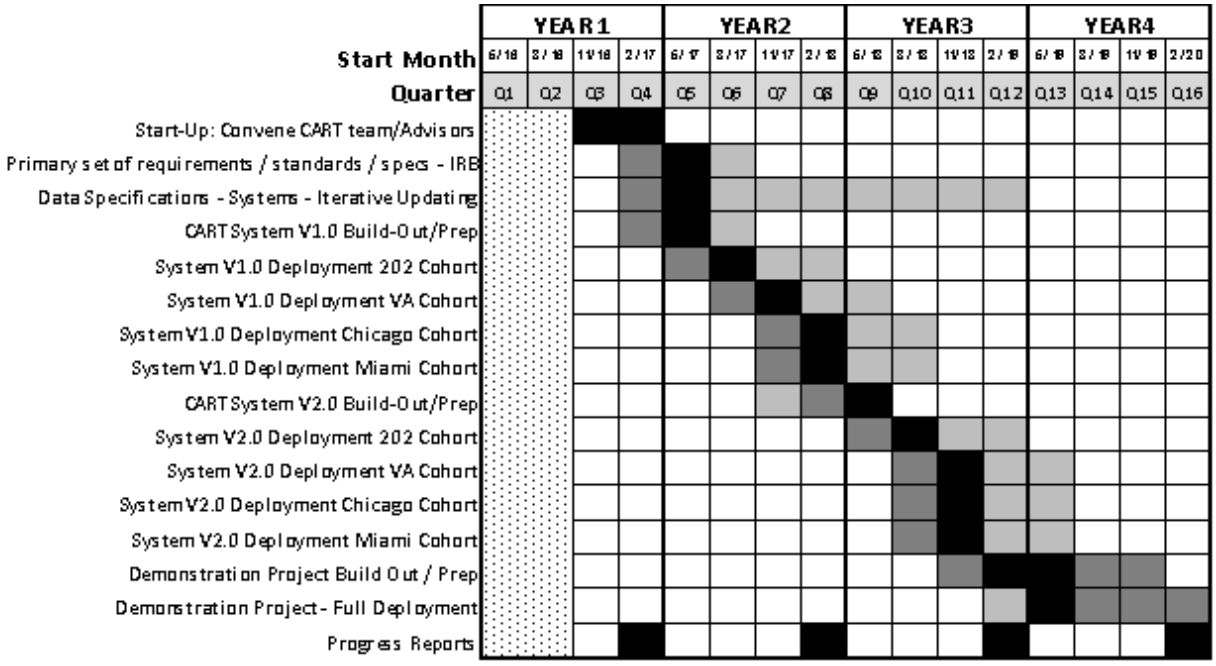
2. Design and plan the illustrative study protocols for the final Demonstration

Project (DP). This will entail further formulating the DP (Aim 5) to test our CART system. Our AiP hypothesis is that *the multi-domain data generated by the CART system provides the basis for sensitive prediction of loss of* independence *or need for higher levels of care.* This key aim will be informed by close collaboration and consultation with end-users, researchers, clinicians, device and application industry experts, and government agencies.

3. Design the infrastructure and data systems necessary for the illustrative study protocols needed for the final Demonstration Project. This involves tuning the end-to-end infrastructure and technical systems (home sensing environment, hardware, software, communications, analytics) to support the CART-equipped homes and their residents through *all phases of the program* leading to the Demonstration Project.

4. Develop and iteratively refine the infrastructure based on initial design, study requirements, user-testing and iterative system deployments. This aim includes assuring usability and acceptability of hardware and software technology, communications and feedback interfaces for the entire user ecosystem (older adults *and* researchers), and incorporates supporting remote configuration and deployment of software and hardware tools based on factors such as health status, home environment, or user preference.

5. Develop, execute, then analyze and share the results of the Demonstration Project. The DP will enroll 360 participants residing in 240 homes located at four demonstration sites representing those most challenged to AiP: low income octogenarian section 202 housing residents, veterans living in non-metropolitan areas, and African Americans and other minorities living in Chicago and Miami. This will be a stringent test of scalability for Phase II. Methodologies and results will be widely disseminated.



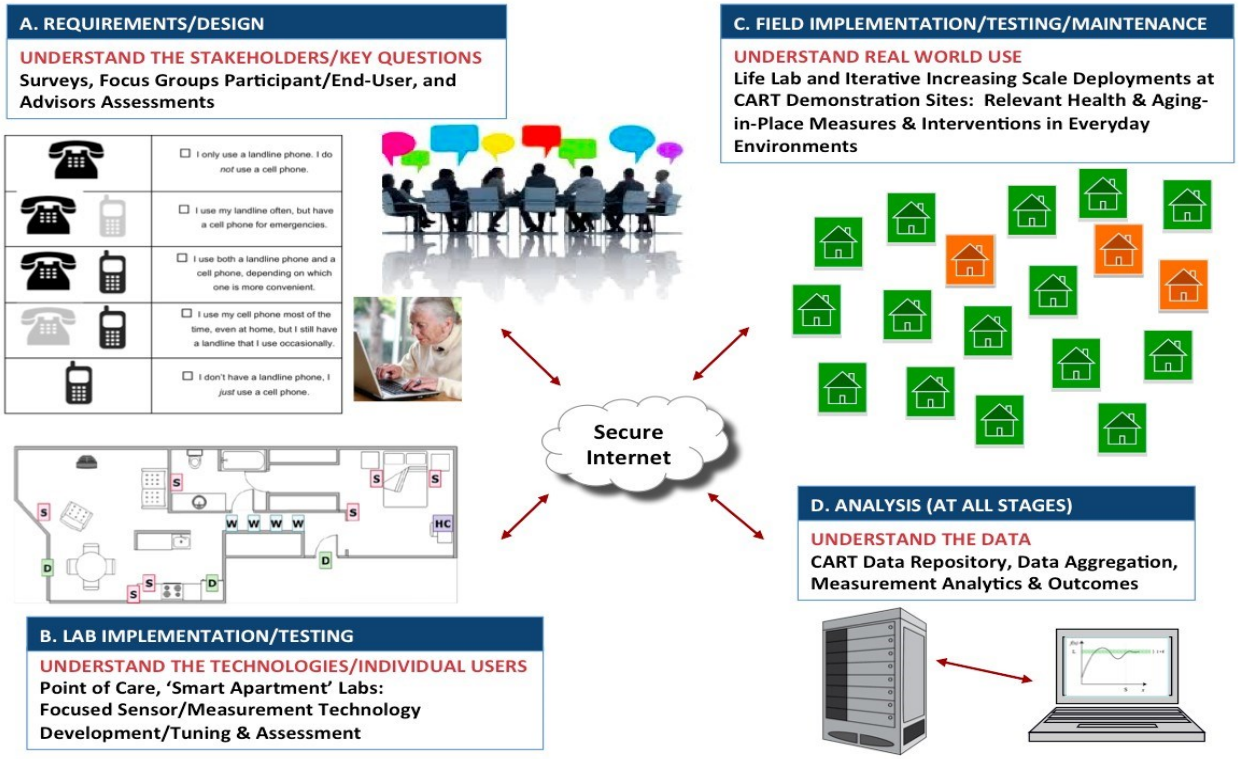
Scientific Rationale and Significance

Significance of the Problem, CART and Background Work Accomplished

As noted in the introduction to the specific aims, the major need for CART has grown out of the realization that a response equal to the profound impact of the "age-wave" on our health systems and providers is needed. The conceptual framework for reaching this conclusion has roots that go back over a decade. The PIs of this application and their organizations were integrally involved in framing this early discussion. In 2001 (before the iPhone, Facebook or Fitbit were known) the National Research Council contracted with NIA to conduct workshops on applications of technology needs of the aging population. Out of that effort a series of papers were compiled that included an important review authored by Eric Dishman of Intel and colleagues ("Everyday Health: Technology for Adaptive Aging") [8]. The review pointed out both the promise and the key challenges of health-related technologies research: 1) Imagination: Moving beyond today's clinical and computing models; 2) Identification: Finding and prioritizing problems to pursue; 3) Iteration: Concept testing and refinement; 4) Infrastructure: Deep dives on enabling technologies; 5) Interfaces: Exploration of human-machine interaction; and 6) Integration: Testing whole systems in situ. Several other early reviews pointed out the considerable promise of many individual technologies and the proliferation of 'smart home' demonstrations and small pilot studies, but also concluded that there needed to be more work on integration and scalable, real world demonstrations of efficacy and effectiveness [9-13].

ORCATECH. Accordingly, beginning in 2001 and formally recognized in 2004 as a NIA Roybal Center (The Oregon Roybal Center for Aging and Technology (ORCATECH); Co-PIs J. Kaye, OHSU and E. Dishman, Intel), ORCATECH was established to address this gap in integration and evidence building. Grounded in knowledge of what is needed to move the field forward, several key ORCATECH goals have been the focus of our research: 1) Supporting a unique *infrastructure and process* that facilitates developing and translating basic real-world, real-time social, behavioral and biological knowledge about aging independently using state of the art technology and engineering; 2) Advancing the ORCATECH use-inspired *Life Laboratory model* for technology-based health monitoring and support of independent aging in individual residences and communities, incorporating leading-edge event and activity sensing and pervasive computing (**Figure 1**); and 3) Accelerating the process of development, translation and dissemination of evidence-based knowledge gained through innovative public private partnerships, cross-disciplinary collaborations and recruitment of new talent into the field.

Figure 1. ORCATECH provides four key domains of expertise and functionality necessary for initiating and completing CART system development: A. **REQUIREMENTS / DESIGN** – Expertise for incorporating the input of all key stakeholders; **B. LAB IMPLEMENTATION / TESTING -** Controlled environment laboratories for focused testing of technologies and systems in isolation or with individual users; **C. FIELD IMPLEMENTATION / TESTING / MAINTENANCE –** The homes of the Life Laboratory volunteers for real-world testing**;** and **D. ANALYSIS (AT ALL STAGES)** - Qualitative and quantitative analysis of the data as well as the meta-data of the system function itself.



These goals have been successfully addressed through a variety of activities including facilitating research among a number of federally funded (NIH, VA, NIST, NSF) grants using multiple mechanisms (e.g., NIH grants such as R01, P30, R03, R21, SBIR; see http://grantome.com/ for summaries: P30AG024978, RC1AG036121, U01AG10483, R01AG024059, R01AG042191, NSF #1111722, NSF #1215850), our NIA Roybal Center pilot grants, foundation support (RWJF, Alzheimer's Association) and novel industry partnerships (e.g., Intel, VGo, VTECH, Microsoft, Eli Lilly). The experience of ORCATECH along with the continuing evolution of "digital" or "eHealth" has confirmed that the model of using the tools of pervasive computing in the home and community to facilitate independent living is likely to be transformative across a wide array of fronts ranging from discovery of new quantitative phenotypes to acceleration of clinical trials in ecologically valid settings. To this point, ORCATECH has pursued a number of specific instances of evidence-building focusing on high impact areas such as cognition, mobility, medication taking, sleep, social engagement and user interaction. [10, 14-84]. Results of these efforts show great promise for providing continuous real-time data that can be used to detect meaningful clinical change and act on these changes in a timely manner.

Despite this promise, one of the most important remaining challenges to the field is to bring this technology and approach into the mainstream of the clinical research enterprise; to realize this potential beyond single smart homes and small demonstration projects even beyond the 100's of homes that ORCATECH has engaged thus far. ORCATECH has been involved in the effort to scale the approach on a number of fronts. We continue to build-out our model, focusing largely on specific health conditions or populations where each installation, after being used for a specific study (e.g. a study of mild cognitive impairment), remains in place after study completion providing years of detailed, long-term continuous health and activity data (up to seven years now), thus building the quantitative human aging data base or "phenome". We have begun Life Lab installations at remote sites (Victoria, BC), further testing the scalability of this approach. This incremental, 'opportunistic' model of scaling out the Life Laboratory over time has provided exceptional insight into the requirements for multiple use cases and the infrastructure needed for CART activities.

It is clear that there is a need for a new approach to building the evidence that takes the lessons learned from past efforts and provides the opportunity to build a responsive, durable research infrastructure and methodology that takes advantage not only of current technologies and systems, but also can incorporate inevitable future developments. What is needed is a research enterprise that mindfully moves the abundance of theory and foundational work completed thus far into larger scale real-world deployments and test beds, both at the level of the deployments themselves, but more importantly, ultimately in the numbers of researchers, health care providers and systems and the older adults who may gain from these technologies.

Research Design and Methods

CART is a four year non-randomized longitudinal infrastructure development and validation study, made up of participants recruited from 4 different sites (OHSU, Portland VA, Rush University Medical Center, and University of Miami). Consented participants will complete yearly assessments which will review neuropsychological and medical changes (see Baseline and Annual Assessment Visits listed below), have unobtrusive monitoring systems installed in their homes to detect behavioral changes over the course of the study (see Platform Installation Visits listed below), and complete online surveys throughout the duration of the study (see Weekly Health Update Questionnaire listed below). This study does not include an intervention.

In total, once enrolled, a subject's participation will last up to 3 years unless they choose to withdraw before the end of the study.

This protocol does not involve "usual care" as it is a naturalistic study, for this reason there will be no entry made into participant medical records (or medical records created for participants who are not enrolled in the VA system).

Participants may be withdrawn from the study if they do not adhere to the study protocol.

Study Visit Table

	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	X		X	X	X	
Modified Cumulative Illness Rating Scale (CIRS)	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	
CART Platform Installation		X				
Device Usability Evaluation			ONLINE	ONLINE	ONLINE	
CART Participant Experience Survey			ONLINE	ONLINE	ONLINE	
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**

Screening Phone Visit (*20 minutes*)

Potential participants will be contacted by phone after indicating they are interested in learning more (or 2 weeks after mailing with no response) about the CART project. Potential participants will have information about the project shared with them and then will be asked some basic screening questions (see Phone Recruitment Script).

Baseline Home Visit (*2-3 hours*)

At the 1st home visit, study staff will conduct the consenting process. After consent and HIPAA forms are signed, the remainder of the baseline visit will involve collecting demographics and health information as well as completing a number of assessments. In-home assessments may be completed with the use of an encrypted study (i.e.VA or OHSU) laptop or tablet to allow for online data entry through RedCAP's https web-interface and/or may be completed on paper and entered into RedCAP (via https web interface) at a later time. Any assessments requiring pen and paper versions to be uploaded to the RedCAP database will be scanned using study approved devices, uploaded to the RedCAP database, and then deleted from the study device. All in-home assessment sessions will be audio recorded to allow for review of assessments and further analysis. Audio recordings will be created using a handheld recorder. Recorded media will be kept in a locked bag until it is dropped off at OHSU at a locked office for upload to the secure database. See **Study Visit Table** above for more details regarding study visit assessments.

At the baseline home visit, study participants will have their photograph taken using an encrypted study device (laptop or tablet). The photograph will be uploaded via https web interface to the ORCATECH Management Console (OMC

see Data Management section for more information) with the participant's 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. After the photograph is uploaded to the OMC it will be deleted off the local study device. In turn, study participants will be provided a document with contact information and photographs of study staff who may contact them during the course of the study.

V1.0 Platform Installation Visit (*1-3 hours*)

The V1.0 platform installation visit will occur within 4 weeks of the participant's consent into the study. This visit will involve setting up the following technologies at the participant's home:

- **Hub computer** (Raspberry Pi 3 Model B): This device receives and transfers all data collected at the home, via secure VPN connection, to servers at OHSU. The hub computer broadcasts a wireless network in the home, acts as a client to a wireless or wired router, and checks in with ORCATECH servers to ensure it is up to date and the device is properly identified.
- **Motion sensors** (PIR – passive infrared, NYCE Control): One motion sensor is installed in each room of the home to capture activity data, a series of 4 is installed in a hallway to detect walking speed, and contact switch sensors are placed on egress doors to detect when participants leave their home. Data from these sensors is collected by the hub computer using a Telegesis Zigbee dongle, then data is transmitted securely to servers at OHSU via VPN. If the hub computer is unable to transmit data at the time of collection, data will be cached locally in a MySQL table until an internet connection is restored.
- **Medication tracking pillbox** (TimerCap iSort): This pillbox is designed to record timestamps of when the lids of the pillbox are opened or closed and transmit the information to the hub computer via BLE (Bluetooth Low Energy). If the pillbox does not have a connection to the hub computer, data is cached locally to the device until the next successful connection. Data is then transmitted securely to servers at OHSU via VPN. If the hub computer is unable to transmit data at the time of collection, data will be cached locally in a MySQL table until an internet connection is restored.
- **Wireless scale** (Withings Body Cardio): This scale tracks weight, heart rate, body composition metrics, and pulse wave velocity. The scale connects to the wireless signal from the hub computer to transmit its data directly to Withings servers. If the scale is unable to connect to the Withings servers, data is cached locally to the device until the next successful connection. ORCATECH servers poll Withings servers for new data via API calls, then store for data analysis. [Note: Weight only will be

provided in participants with a pacemaker as other features will be turned off.]

- **Wrist worn fitness tracker** (Withings Steel, Withings Steel HR, Fitbit Flex, Fitbit Alta HR, Fitbit Charge 2, etc.): The wrist worn wearable device collects physical activity data both in and out of the home. Several brands and models of wearables will be used in this study.
    - **Withings:** Withings wearable devices collect physical activity data and sent via BLE to the hub computer. If the wearable is unable to connect to the hub computer, data is cached locally to the device until the next successful connection. The hub computer will transmit the data to both the Withings (HTTPS) and ORCATECH (VPN) servers. If the hub computer is unable to transmit data at the time of collection, the data will be cached locally in a MySQL table until an internet connection is restored.
    - **Fitbit:** Fitbit wearable devices collect physical activity data which is encrypted by the device and sent via BLE the hub computer. If the wearable is unable to connect to the hub computer, data is cached locally to the device until the next successful connection. If the hub computer is unable to transmit data at the time of collection, the data will be cached locally in a MySQL table until an internet connection is restored. The hub computer send the encrypted data to the Fitbit servers via an HTTPS connection. The ORCATECH servers poll Fitbit servers for new data via API calls to store for data analysis.
- **Driving sensor** with built in cellular signal (Automatic Pro): The driving sensor collects driving pattern information from vehicle models from 1996 and newer, excluding electric vehicles. Data from the device is transferred via cellular network to the Automatic servers. The ORCATECH servers poll the Automatic servers for new data via API calls, then store for data analysis.
- **Computer use monitoring software** (Worktime Corporate): Computer use monitoring software is installed on participant computers. This software collects information about computer sessions. Data is transmitted to ORCATECH servers via TCP connection.
- **Sleep monitor** (Emfit QS) [CART Platform V2.0 Device – added in 2019]: The Emfit QS will be placed under the mattress of study participants. This device will help to enhance and validate the sleep data already being collected by the wrist worn fitness tracker and motion sensors. The Emfit QS collects heart and breathing rates, heart rate variability, and movement activity (such as tossing and turning). Data is transmitted to the Emfit servers via HTTPS. Data will be transferred to ORCATECH servers daily via Emfit API calls

Weekly Health Update Questionnaire (*5-15 minutes weekly*)

On a weekly basis, participants will be emailed a short 13 question survey (see Weekly Questionnaire) via Qualtrics Survey Platform, with follow up questions for YES responses. These questions are designed to augment the behavioral data collected by the CART Platform. Data from the survey are stored on the Qualtrics servers which is polled by ORCATECH servers via API calls to store for data analysis. Study participants may be contacted for further information about their responses to this questionnaire, including being asked to provide a release for medical records related to events captured on the questionnaire.

Online Surveys (*Approximately 30min -1 hour over the course of each year)*
Each year, study participants will be emailed several online surveys via the Qualtrics Survey Platform. These surveys are emailed instead of done in person in order to shorten the in-home visits and to allow for participants to feel free to share study concerns on the Device Usability Evaluation and CART Participant Experience Survey.

Annual Home Visit (1-*2 hours*)

The annual home visit will involve updating demographics and health information as well as completing a number of assessments. See **Study Visit Table** above for more details.

V2.0 Platform Installation Visit (*1 hour*)

The V2.0 platform installation visit is designed to update the homes to the V2.0 platform which will update V1.0 and incorporate new technologies anticipated to come on-line in the next few years. Additional technologies may be added and changed technologies will be removed and replaced with newer versions. If a participant is consented into the study after the V2.0 platform is being deployed, they will have a combined V1.0, V2.0 visit to ensure the most current technologies are installed into their home.

Technology Uninstall Visit (.5-1 *hour*)

At this visit, technology will be uninstalled from the participant's home.

Data Analysis

The Data Core supports all the analytic aspects of the development research and DP itself. As discussed above, raw data can ultimately be specified at many levels of

function and needs to be carefully considered in any analytic approach.

Statistical modeling and analysis must be tuned to appropriately query different potential hypotheses and specific research aims. Our experienced Data Core team has applied many approaches to in-home monitoring and related data including mixed effects models, latent trajectory models, generalized mixed effects models, negative binomial models, Boolean network dynamics, and Markov models, so that the data can be meaningfully translated for advancing clinical knowledge. Beyond these modeling techniques, some of the suitable analytical methods we anticipate to utilize for CART data include creating composite scores for each key life domain in order to maximize the sensitivity to observing change. We also will to use 'big data' analytics (e.g., SVM and random forests classifiers) to deal with the high- dimensionality of the data. Our team has a solid record of publishing and disseminating the results derived from hybrid analysis of home-based sensed and traditional clinical data in peer review journals. We will disseminate analytic approaches used (programs, algorithms and general description of methods) along with data to facilitate wider usage and further development of analytics in our field.

Study Population

Number of Subjects

Total: The total number of homes to be enrolled in this study is 400 for the final demonstration project. If participants drop out or withdraw from the study before the demonstration project in the final year (year four), additional participants will be recruited to ensure total enrollment at that time is 400 homes. We anticipate that some of these homes will have two residents, for a total of up to 800 enrolled study participants.

OHSU: We expect to enroll approximately 100 study homes or up to 200 study participants who are of low income, predominantly living in Section 202 housing.

Portland VA: We expect to enroll approximately 100 study homes or up to 200 study participants who are veterans and their spouse or cohabitant.

Rush University Medical Center: We expect to enroll approximately 100 study homes or up to 200 study participants who are African American.

University of Miami: We expect to enroll approximately 100 study homes or up to 200 study participants who are largely African American or Latino.

Inclusion and Exclusion Criteria

Inclusion:

1) 62 years or older;
2) Living alone or with a cohabitant over age 18 (cohabitant will also be required to

consent to fully participate in the study);
3) Larger than one-room apartment;
4) Not demented;
5) Age and education adjusted MOCA > 18;
6) Household has the ability to have a reliable broadband internet connection;
7) Existing computer or email user, can be waived at site PI discretion.

Exclusion:

1) Conditions that would limit physical participation at entry to study (e.g. wheelchair bound);
2) Any uncontrolled medical condition that is expected to preclude completion of the study, such as late stage cancers.
3) More than two people live in the participant's residence (overnight visitors are acceptable).
4) GDS score > 5

Subject Identification/Recruitment

Recruitment will primarily consist of presentations to potential groups of participants and mailings/phone calls to existing contact repository participants at the involved study sites. Presentations will involve an explanation of the study and potential participants will be able to provide their name and phone number for a phone screening follow-up call. Information about the CART project, including eligibility criteria will be made available on the CART and ORCATECH websites, along with contact information for each site. Additional site-specific recruitment descriptions will be included in individual site protocols as appropriate.

Initial eligibility will be determined during a phone screening visit with each study participant.

Site Specific Recruitment Information

OHSU: This cohort will be focused on low-income octogenarians. Participants will be recruited from local Section 202 housing, starting with the Union Manors who have partnered with us for this project. In addition, any existing ORCATECH Life Lab volunteers (IRB#2765) who are low income may be contacted for participation in this project.

Portland VA: This cohort will be focused on veterans and will also include a cohabitant if they live with one. Any veteran who meets the specified inclusion/exclusion criteria will be offered participation in this study regardless of if they are enrolled in the VA system.

Recruitment flyers will be posted in bulletins, newsletters, and social media platforms within the VA as well as in veteran-affiliated entities and communities.

CAPRI, JVL, CDW/VINCI and CPRS will be used to screen for eligible Veterans based on age, location and health history.

In addition to the previously stated inclusion/exclusion criteria, the VA CART site aims to include a majority (>50% households) of subjects living outside of a major metropolitan area, which will be determined using the United States Department of Agriculture Rural-Urban Community Area Codes (RUCA) classification system (https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx). In order to maintain study feasibility in managing installed technological infrastructure, VA subject recruitment will be limited to those living within a 250 mile radius. For those out of range, individual exceptions can be made at the PI's discretion.

These veterans will be initially recruited via letters from a clinician who has a clinical relationship with the individual. We will be sending a recruitment letter to patients that have been seen at the VAPORHCS within the past 5 years. Recipients will be asked to reply to the letter, letting the research team know whether they may be contacted by phone regarding this study; the research team may then contact those candidates that have given their express permission to be contacted, and recruitment will proceed as above. The research team may contact recipients to confirm that the letter has been received; this is stated within the letter.

We also plan to make use of Dr. Lim's "VAPORHCS Sleep Disorders Data Repository" (Repository Number #3636). This repository contains names and contact information of people interested in further research participation. All subjects included in the repository have consented to being contacted for opportunities for participation in research. Initial contact with potential participants will be made by the study PI, who is also a co-investigator on the repository. The ICF and flyer will be mailed to interested candidates, and recruitment will proceed as above. A Data Use Agreement will be executed before data from this repository is received by the CART VA site team.

Additionally, the study PI and study site coordinator will give recruitment presentations at community locations in non-metropolitan locations to recruit additional veterans who may not have been identified using CPRS or the Sleep Disorder repository. Presentation materials will be uploaded for approval at a later date, prior to any presentations.

In households where the study participant lives with a cohabitant, the cohabitant will also be consented into the study.

Rush University Medical Center: This cohort will be comprised of urban African American seniors. Participants will be recruited from the existing Minority Aging Research Study (MARS; R01AG22018; L. Barnes, PI).

University of Miami & Weill Cornell Medicine: This cohort will be focused on

diverse socially isolated, low income seniors. At the University of Miami, participants will be recruited from the community, as well as the existing CREATE registry (CREATE; P01AG17211; S. Czaja, PI). At Weill Cornell Medicine, participants will be recruited from the community as well as existing aging studies at the Center on Aging and Behavioral Research.

Informed Consent

Upon arriving at a participant's home, the consenting process, including HIPAA form, will occur in-person via a paper consent form. Consent paperwork will be written in lay terms. After study staff have explained the consent process and study procedures in lay terms, we will ask the potential participant to explain the study in his or her own words. We will continue this process until both parties (the research staff and the consenting participant) feel they have reached mutual understanding. Contact information will be provided to potential participants for any questions they may have at any point before, during or after study participation.

If at any point it becomes necessary to re-consent or re-authorize a study participant, this may be done by mail instead of in person. All related materials (such as phone scripts and cover letters) will be approved by the IRB prior to their use.

We will minimize the possibility of coercion or undue influence by informing participants during the consenting process that participation in the study is voluntary and that they can quit at any time, and we will confirm that they understand this point by asking them a question. Compensation amounts have been kept to a minimal amount to reduce the possibility of inappropriate financial influence.

Risks and Side Effects:

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 through the body to perform some of its measurements such as fat mass, which may interfere with a pacemaker or other medical device. Participants who have a pacemaker 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 a participant has one. If a participant gets a pacemaker during the course of the study, they will be asked to alert the 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 a participant's home may fall from surfaces and potentially cause injury or damage. These sensors weigh less than 0.25 pounds and are the size of a man's thumb. Study staff will do their 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.

By storing or sending personal information on your computer there is some risk that it may be accessed by any 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.

The repository housing data from this protocol (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.

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

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

Participant Safeguards:

This study will not include any vulnerable populations. We will include older adults, but will exclude anyone with a cognitive impairment that would disqualify them from consenting for themselves.

Benefits:

Study participants will receive monetary compensation of up to $100 per household that can be used towards maintaining internet connection. Participants may find they feel less isolated due to visits from study staff. There is otherwise no direct benefit associated with participation in this study, although older veterans living far from medical care may benefit from the information gained from this study in the future.

Protected Health Information:

Information from patient VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings may be used to determine if a patient is eligible for this research study.

Certain HIPPA identifiers will be utilized in this study, including subject: name, address, date of birth, phone number, last four digits of social security number (this serves as the subject's medical record number), vehicle identifier (if participant drives a vehicle that is new enough for the driving sensor component of the study, this information is automatically provided by the device), Internet Protocol address number, email address, and full face photographic image.

This PHI is the minimum required in order to conduct the proposed research, and cannot be further reduced. Subject name, address, phone number and email address will be necessary in order for the subject coordinator and technician to make home visits and to confirm subject identification for the purposes of neuropscychometric assessments and for installation and maintenance of the CART monitoring platform. The last four digits of the subject's social security will be collected as it serves as their VA medical record number. This information will be needed in order to clarify inclusion/exclusion criteria, including changes in the subject's medical status or contact information.

Digital images and audio recordings will be collected on all study participants. Digital images will be used by study staff as a visual confirmation they are visiting with the correct participant. Audio recordings are being collected from the assessment visits to provide training data for an automated speech recognizer that may eventually be able to score the assessments automatically.

Questionnaire and survey data collected by the study may be individually identifiable, but is critical for data analysis (i.e. if there is a period of time where we have no sensor data from a study home, but a participant has reported they were away from home for that period, there is an explanation for the change in sensor data). When study participants answer online surveys they receive via email for the study, their IP address is included in the information that is recorded by the Qualtrics software.

Multi-Site Study Concerns

CART Coordinating site:

OHSU: *Primary CART PI:* Dr. Jeffrey Kaye, kaye@ohsu.edu

This site is the coordinating site for the overall CART project. This site is responsible for the majority of the protocol creation, technical development and data analysis. This site will recruit a cohort of low income participants.

Additional CART sites:

Portland VA:	*Site PI:* Dr. Lisa Silbert, silbertl@ohsu.edu
Rush University:	*Site PI*: Dr. Lisa Barnes, lisa_l_barnes@rush.edu
Weill Cornell Medical:	*Site PI*: Sara Czaja, sczaja@med.miami.edu
University of Miami	*Site PI:* David Loewenstein, dloewenstein@med.miami.edu

These additional CART sites are responsible for recruiting cohorts (as described in the Study Population section) into the CART project.

VA Research

The activities considered to be VA research activities are those specifically relating to the participants recruited for the Portland VA site. The Portland VA Site PI and Study Coordinator will be responsible for advertising and recruiting for these study participants. Some of this work will be done onsite at the VA, though much will be done in the field in the communities of the Veterans being recruited into the study. The assessor (who will be paid via IPA) will conduct assessments for the study in the homes of Veteran study participants. The technical research assistant for the VA will primarily spend their time installing technology in Veteran participant homes in the field. There are also a number of staff from the OHSU CART site who have become WOC employees to be able to assist the VA site with recruitment, screening, and home technology installation as needed. These activities will not occur onsite at the VA, but instead either from OHSU or in the field with study participants.

Non-VA Research

All CART research other than that conducted with VA study participants is considered non-VA research. The majority of the protocol creation, technical development and data analysis will occur outside of the VA. Each study site is responsible for their own cohort of study participants, though they will have support from the CART Coordinating site.

Resources Available

The VA site PI, Dr. Lisa Silbert, has been given 3/8 time to work on this project. Full time study site coordinator, assessor (paid via IPA), and technical research assistant staff will be working on this project. Office space at the VA will be provided for the study site coordinator and technical research assistant. Study visits will primarily occur in the homes of study participants.

Commercial Development

Information including any photographs or audiotapes about participants or obtained from participants in this research may be used for commercial purposes, such as making a discovery (e.g. using analysis from audio files) that could be patented or licensed to a company or helping a company to do research. There are no plans to pay subjects if this happens. Subjects will not have any property rights or ownership or financial interest in or arising from products or data that may result from their participation in this study. Further, subjects will have no responsibility or liability for any use that may be made of their information.

Costs To Subjects

To participate in this study, participants are required to provide internet service to their home. They may incur a cost for this service. There are no other costs to research subjects.

Subject Compensation

Participant households will receive a $50 per month stipend (up to $100 to VA participant households since the majority of them are expected to be 2 person homes) to support their participation in the research during months they have the CART Platform installed in their home for 7 or more days in a given month. This payment is to compensate participants for their time and help defray the cost of the required broadband service.

Participants will be compensated by their site, using the site's preferred method. OHSU participants will receive a ClinCard which is a reloadable debit card which will be loaded at the end of each month of their participation. Portland VA participants will receive EFT or cash voucher at the end of each month of their participation.

These payments are designed to help study participants maintain an internet connection to their homes and compensate them for the time they will spend on study activities.

Privacy and Confidentiality

For those enrolled and consented into the VA site, study data will be stored in the central CART study database. This information will be stored under a unique identifier. This information can only be accessed by study staff using their own unique logins for the database.

All paper copies of data will be kept in a locked cabinet in a locked office at the VA. Electronic data for VA study recruitment will be kept in a secure folder on the VA network, accessible only to the PI and the Study Site Coordinator.

Data obtained from the CART platform will be transmitted and kept on an OHSU secure server as part of the CART repository mentioned earlier in this protocol. This data will be password protected and only accessible behind a firewall. This data will be housed at OHSU at the conclusion of the study. Raw data will be kept at OHSU.

NACC (National Alzhiemer's Coordinating Center) data collected into REDCap will be sent securely to NACC. Participant 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 age. Study participant identity will not be disclosed unless you give separate and specific consent for it.

Certificate of Confidentiality

The CART project has a Certificate of Confidentiality from the NIH to ensure sensitive information collected during the course of the study is protected against subpoena. NACC has a Certificate of from the NIH to ensure sensitive information collected during

the course of the study is protected against subpoena.

Information Management

Paper data will be stored in locked filing cabinets in restricted-access areas. While in transit between a participant's home and the study site, all paper documents such as informed consent forms and HIPAA authorizations will be secured in a locked bag.

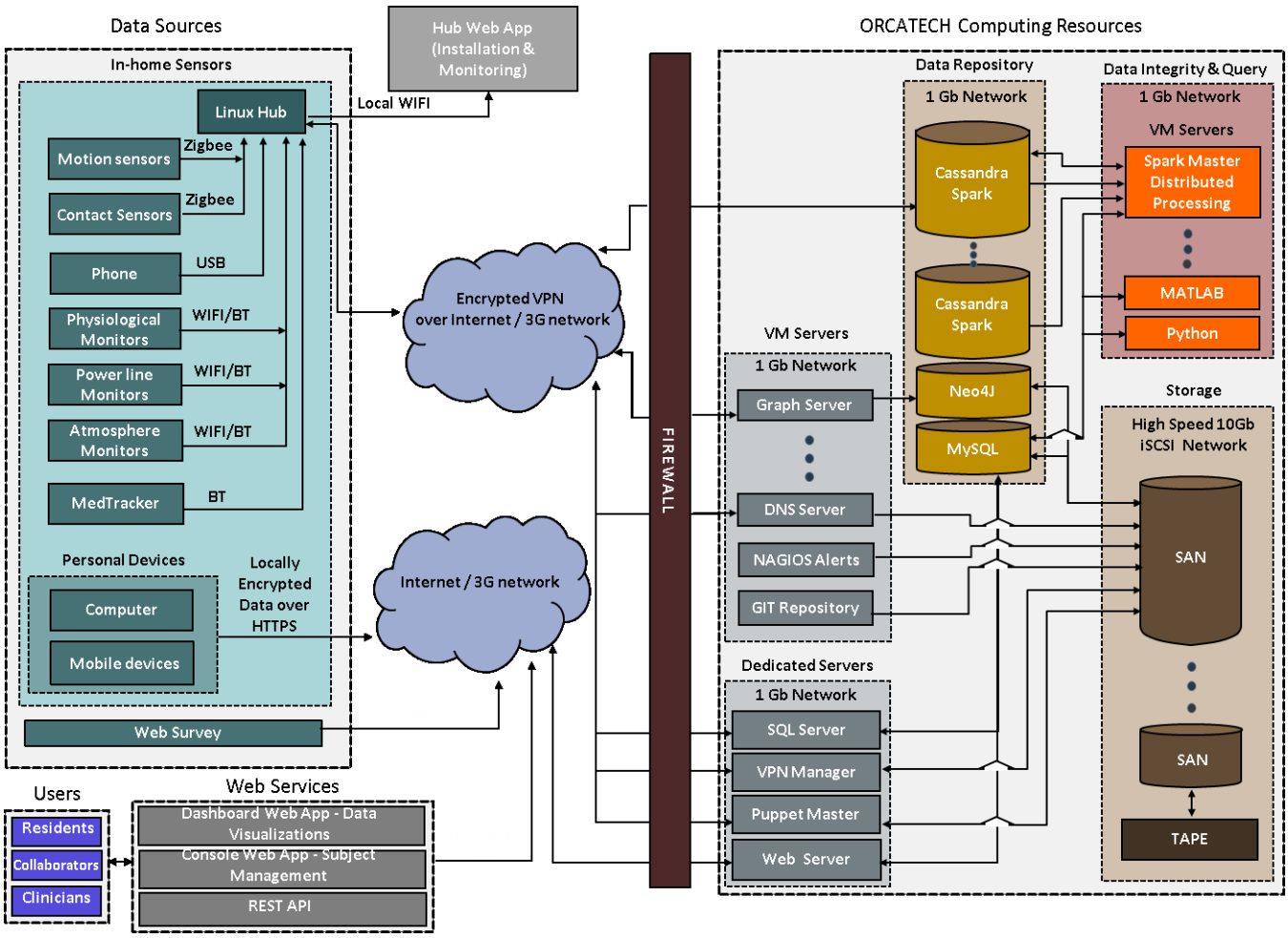
Neuropsychological and clinical data will be entered via https web interface into a secure RedCAP database on an OHSU research server and will later be copied via API to ORCATECH data servers. Survey data will be collected via the Qualtrics Survey Platform (FIPS 140-2 compliant transfer) via https web interface into the Qualtrics Servers and will later be copied to ORCATECH data servers via API call.

Automatic.com will collect driving data over cellular network (FIPS 140-2 compliant transfer) which will be stored in their servers and will later be copied to ORCATECH data servers via API call.

Nokia/Withings scale data is sent to Nokia over wireless connection (FIPS 140-2 compliant transfer) and will later be copied to ORCATECH data servers via API call.

CART Platform data are time-stamped and stored locally on the hub computer in a secure, password-protected MySQL database. Data are encrypted and uploaded from the homes to the OHSU secure research server on a regular basis via secure VPN, but may also be polled on demand (see V1.0 Platform Installation Visit section for more detailed information about data collection and transfer path to OHSU servers). Research staff may access the data from the central data server at OHSU, as well as directly from the sensor computer using secure (encrypted) commercial remote-connection software.

The data, study cohorts, and remote installations are managed using the ORCATECH Management Console (OMC) https web interface, which is a password-protected multi-tiered remote monitoring application built from Open Source tools including PHP and MySQL. This tool allows staff to view project-related participant and home information, track recruitment and subject contacts, track inventory, generate alerts for upcoming scheduled visits (or unscheduled maintenance visits), view the "health" of the system (e.g., outages), and look at summaries of the data over time. Each CART site manages their own subjects and cannot see details for the other sites, however the OHSU coordinating site will be able to see all CART subjects and homes to be able to assist with technical issues. Home platform data is reviewed for the functional integrity of the system as a per-subsystem summary on a weekly basis by the CART study staff at each site.



Transfer of Data Ownership

Upon signing the study consent form, ownership of all future data will transfer to the CART study Principal Investigator, Dr. Jeffrey Kaye at OHSU and will be the responsibility of Dr. Jeffrey Kaye at OHSU.

Originals of paper records will be maintained at VAPORHCS in a locked filing cabinet in a locked room.

Data and Safety Monitoring Plan

Safety monitoring will involve periodic review of adverse events (AEs), dropouts, complaints or breaches of confidentiality. Subjects will be encouraged to report any potential problems at any time to the research coordinator. The safety of the subject will be monitored during the assessment visits to ensure the subject is not having any adverse events. Adverse events will be judged by the monitor as related, possibly related or unrelated to the study procedures. Serious adverse events (SAEs), unanticipated problems (UPs) and protocol deviations that are greater than minor will

be reported to the OHSU Institutional Review Board, per OHSU IRB policy.

Safety data collection will begin with the first report of a problem or potential problem. Safety data will continue to be added as staff becomes aware of safety issues. The PI and study site coordinator will review safety data quarterly.

Dr. Silbert will oversee the safety data. We do not foresee any reasonable conditions that would trigger an immediate suspension of the research.

Step-by-Step Guidance on Conducting the Study

Recruitment

Initial screening data for the VA CART site will be pulled using VINCI and CPRS. This data will be used to pre-screen patients for potential eligibility, starting with those who have been seen in the past 5 years, live within a 250 mile radius of Portland, OR, and who have been seen at the VAPORHCS Geriatrics or Sleep Disorders Clinics. These patients will be pre-screened to determine potential eligibility before we mail them an IRB-approved recruitment letter from their physician; this is in accordance with the study's OHSU HIPAA Waiver and with the VAPORHCS Waiver of Authorization for Screening/Recruitment purposes. This letter will inform recipients of the study, and request permission to contact recipients regarding the study. The research coordinator will not be permitted to speak with recipients about the study without first receiving their express permission via a return letter. The research coordinator may contact the recipient to confirm that the letter was received.

Some candidates may be found by using the VAPORHCS Sleep Disorders Data Repository maintained by Dr. Miranda Lim (#3636). The records included in these repositories will be pre-screened for potential eligibility; likely candidates will be contacted by telephone by the research coordinator and informed of the study. Interested candidates will be pre-screened as described above, and potentially scheduled for an enrollment visit.

Initial contact may also occur by telephone if a potential subject contacts the study team about this study after learning about it in the community, e.g. by reading an IRB approved flyer, seeing the flyer text on a recruitment website, or attending a community presentation. In this event, the research coordinator will conduct the telephone screening questionnaire. If candidate proves likely to be eligible, the study materials mentioned above will be mailed to the candidate; pre-screening and scheduling will proceed as described above.

Baseline Visit

The baseline study visit will be conducted by the site coordinator or the assessor. Prior to this visit, candidates will have been given an Informed Consent. Candidates will speak the study team member individually in a private space in order to sign the consent forms. Consent will involve agreement to participate in all components of the study. The HIPAA

Authorization Form will be discussed and signed at this point as well. All potential subjects who meet the inclusion and exclusion criteria, consent to participate, and provide authorization for the use of their results will be invited to enroll.

The study team member will use an encrypted study (i.e.VA or OHSU) laptop or tablet to take a digital image of the study participant for use in the participant's profile within the ORCATECH Management Console (OMC) and provide the study participant a paper contact list (with pictures) of study staff. After the visit, the study team member will enter the participant's contact information and picture into the OMC using the https web interface for tracking during the CART study. Once the photograph is uploaded to the OMC, the locally stored photograph on the encrypted study device will be deleted.

The study team member will then administer the baseline assessments. Assessments may be completed with the use of an encrypted study (i.e.VA or OHSU) laptop or tablet to allow for online data entry through RedCAP's https web-interface and/or may be completed on paper and entered into RedCAP (via https web interface) at a later time. Any assessments requiring pen and paper versions to be uploaded to the RedCAP database will be scanned using study approved devices, uploaded to the RedCAP database, and then deleted from the study device. All in-home assessment sessions will be audio recorded to allow for review of assessments and further analysis. Audio recordings will be created using a handheld recorder. Recorded media will be kept in a locked bag until it is dropped off at OHSU at a locked office for upload to the secure database.

Demographics Form	X
CART SES & Employment Form	X
Physical Assessment Form	X
Mobility Form	X
Subject Health History	X
Subject Medications	X
Clinician Assessed Medical Conditions	X
Modified Cumulative Illness Rating Scale (CIRS)	X
OARS ADL/IADL	X
CART Habits Form	X
MoCA	X
Craft Story 21 (Immediate)	X
Benson Complex Figure Copy (Immediate)	X
Number Span Forward (WAIS-R)	X
Number Span Backward (WAIS-R)	X
Category Fluency (Animals)	X
Category Fluency (Vegetables)	X
Trail Making Test, Part A & B	X

Craft Story 21 (Delayed)	X
Benson Complex Figure copy (Delayed)	X
Multilingual Naming Test (MINT)	X
Letter Fluency (F, L)	X
Generalized Anxiety Disorder 7-item (GAD-7)	X
Geriatric Depression Scale	X
TIME PER VISIT	**2-3 Hours**

After the baseline visit is completed, the site coordinator or assessor will notify the technical research assistant who will schedule the CART Platform Installation Visit.

CART Platform Installation Visit

The technical research assistant will visit the home to set up the technology listed in the V1.0 Platform Installation Visit section listed above. Some technologies will not be installed if they are not appropriate for the home. For example, if the study participant doesn't have a vehicle or has a vehicle that does not support the Automatic Driving Sensor, that device will not be installed.

The technical RA will confirm that the participant's email address is properly entered in the OMC so that they will receive the online weekly questionnaire starting the following week.

All installed equipment will be tested to ensure it is working before the technical RA leaves the home. If an issue cannot be resolved, a follow up visit will be scheduled. The technical RA will use the OMC on a regularly basis to ensure that the data from the home looks good and all CART Platform devices are working properly.

Once the CART Platform is installed in a participant's home for at least 7 days, the study coordinator will start issuing monthly $100 payments to the household.

Online Questionnaires

The following assessments will be completed by participants annually online:

Physical Activity Scale for the Elderly (PASE)	X
Pittsburg Sleep Quality Index	X
UCLA Loneliness Scale	X
Lubben Social Network Scale	X
Zarit Burden Interview (Couples only)	X
RAND 36-Item Health Survey (SF-36)	X
ORCATECH Technology Use Survey	X
Device Usability Evaluation	X
CART Participant Experience Survey	X

TIME FOR SURVEYS	30-60 minutes

Online weekly questionnaires are sent by email to study participants Monday mornings at via the Qualtrics platform. Study staff review any items that are flagged and may require a follow up phone call or visit. These items could include health information that will be presented to the study PI according to the DSMP, or information about devices that need to be changed, updated or moved. Study participants may be contacted for further information about their responses to this questionnaire, including being asked to provide a release for medical records related to events captured on the questionnaire (for participants who are enrolled in the VA system, their medical record will be accessed to determine if there is information about the event in question).

Annual Assessment Visits

Once a year, participants will have an annual assessment visit with study staff. The study coordinator or assessor will call the participant to schedule the appointment. Staff will complete the following assessments with participants at this visit:

Demographics Form	X
CART SES & Employment Form	X
Physical Assessment Form	X
Mobility Form	X
Subject Health History	X
Subject Medications	X
Clinician Assessed Medical Conditions	X
Modified Cumulative Illness Rating Scale (CIRS)	X
OARS ADL/IADL	X
CART Habits Form	X
MoCA	X
Craft Story 21 (Immediate)	X
Benson Complex Figure Copy (Immediate)	X
Number Span Forward (WAIS-R)	X
Number Span Backward (WAIS-R)	X
Category Fluency (Animals)	X
Category Fluency (Vegetables)	X
Trail Making Test, Part A & B	X
Craft Story 21 (Delayed)	X
Benson Complex Figure copy (Delayed)	X
Multilingual Naming Test (MINT)	X
Letter Fluency (F, L)	X

Generalized Anxiety Disorder 7-item (GAD-7)	X
Geriatric Depression Scale	X
TIME PER VISIT	**1-2 Hours**

CART Platform Uninstall Visit

When a study participant withdraws from the study or reaches the conclusion of the study, the study coordinator or technical RA will schedule an appointment to remove the CART Platform from the participant's home.

Data Maintenance

Data captured by the CART Platform will be transferred to the ORCATECH servers at OHSU. VA and OHSU study staff will monitor the quality of the data. OHSU study staff will support VA staff as needed for troubleshooting of equipment in participant homes.

Appendix

All relevant documents have been uploaded to the eIRB.

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