

ORIGON HEALTH & SCIENCE UNIVERSITY
Minimal Risk Protocol Template

Principal Investigator:

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1) Protocol Title

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

2) Objectives

This project is focused on the creation of a sustainable infrastructure for the independent aging or 'aging in place' 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 analysis of data using a rapid and reliable data management system.

The CART program will develop and validate its activities using a unique multi-disciplinary 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 this project 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, 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 leading to the final Demonstration Project (DP).** This will entail further formulating the DP (see Aim 5) to test our CART system. Our aging in place 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 age independently: low income octogenarian, section 202 housing residents, veterans living in rural areas, and African Americans and other minorities living in Chicago and Miami. This will be a stringent test of scalability for future larger deployments entailing eventually thousands of homes. Methodologies and results will be widely disseminated.

3) **Background**

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. The amount spent on these services in the United States (in 2012) was \$219.9 billion 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. 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. 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 as yet to be fully evaluated, developed or implemented. Despite indications of high promise, the evidence base remains incomplete. The CART program will create a sustainable infrastructure for the independent aging 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 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.

4) Study Design

CART is a four year non-randomized longitudinal infrastructure development and validation study, made up of participants recruited from 5 different sites (OHSU, Portland VA, Rush University Medical Center, University of Miami, and Weill Cornell Medicine). This study does not include an intervention.

5) Study Population

a) 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: At 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 & Weill Cornell Medicine: We expect to enroll approximately 100 study homes or up to 200 study participants who are largely African American or Latino.

b) 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 > 5

c) Vulnerable Populations

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.

d) Setting

This is a multi-center community-based project involving OHSU, the Portland VA, Rush University Medical Center, the University of Miami, and Weill Cornell Medicine. Recruitment will occur at each of the sites and their surrounding areas.

Study staff at all sites will conduct most participant interactions in the homes of the study participants. Additional research activities such as study equipment preparation, data management, and analysis will occur at the study sites.

e) Recruitment Methods

Recruitment will primarily consist of presentations to potential groups of participants and mailings/phone calls to people participating in research 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.

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. The recruited population will be primarily rural and will be composed of many couples. VINCI and CPRS will be used to screen for eligible Veterans based on age, location, and health history. These Veterans will be recruited via letters from their primary care physicians. We will also recruit through the existing VAPORHCS Sleep Disorders Contact Repository (#3636) and at community presentations where a high number of Veterans are expected to be in attendance. Veterans recruited into this cohort are not required to be enrolled in the VA system.

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.

Participant households will receive a \$49 per month stipend (\$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. Participants will be compensated by their site, using the site's preferred method. OHSU, University of Miami, Weill Cornell Medicine, and Rush participants will receive a monthly gift card or ClinCard (OHSU only) which is a reloadable debit card which will be loaded at the end of each month of their participation. Portland VA participants will receive a cash voucher or EFT 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.

f) Consent Process

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. At the Miami site, Spanish speaking participants will be recruited and consented using translated forms by study staff who are also Spanish speakers.

If at any point it becomes necessary to re-consent or re-authorize a study participant, this re-consent may be done by mail instead of in person.

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.

6) Procedures

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

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	
Modified Cumulative Illness Rating Scale (CIRS)	X		X	X	X	
OARS ADL/IADL	X		X	X	X	
Physical Activity Scale for the Elderly (PASE)	X		X	X	X	
Pittsburg Sleep Quality Index	X		X	X	X	
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	X		X	X	X	
Lubben Social Network Scale	X		X	X	X	
Geriatric Depression Scale (GDS)	X		X	X	X	
Care & Support Assessments						
Zarit Burden Interview (Couples only)	X		X	X	X	
Quality of Life						
RAND 36-Item Health Survey (SF-36)	X		X	X	X	
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 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 (unless these assessments have been administered via another study within the past 6 months). In-home assessments may be completed with the use of a study device (computer or tablet) to allow for online data entry through RedCAP, or may be completed on paper and entered into RedCAP at a later time. All in-home assessment sessions will be audio recorded to allow for review of assessments and further analysis. **See Study Visit Table above for more details.**

At the baseline home visit, study participants will have their photograph taken using a piece of study hardware (computer, tablet, cell phone). The photograph will be uploaded 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. 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. Study staff will verbally give permission to be photographed for this document which will be recorded in the OHSU study documents.

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 sleep monitor 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.

Annual Home Visit (2 hours)

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

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.

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 (1 hour)

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

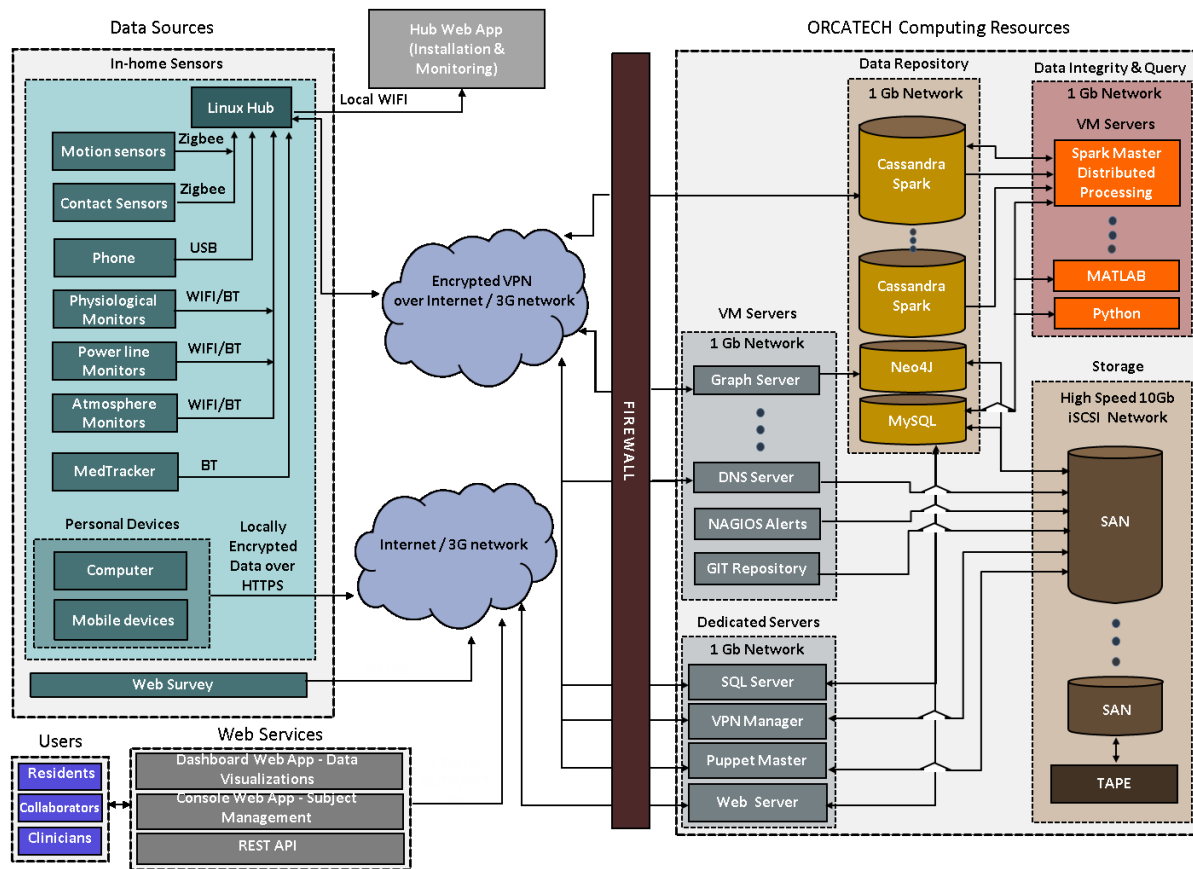
7) Data and Specimens

a) Handling of Data and Specimens

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 stored in REDCap and on a secure database on an ORCATECH research server.

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), 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. 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.



b) Sharing of Results with Subjects

Subjects will be informed of any clinically significant change in their cognitive or functional status as detected by yearly standardized testing.

c) Data and Specimen Banking

All data will become part of the CART repository (eIRB#17189) under this protocol.

8) 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

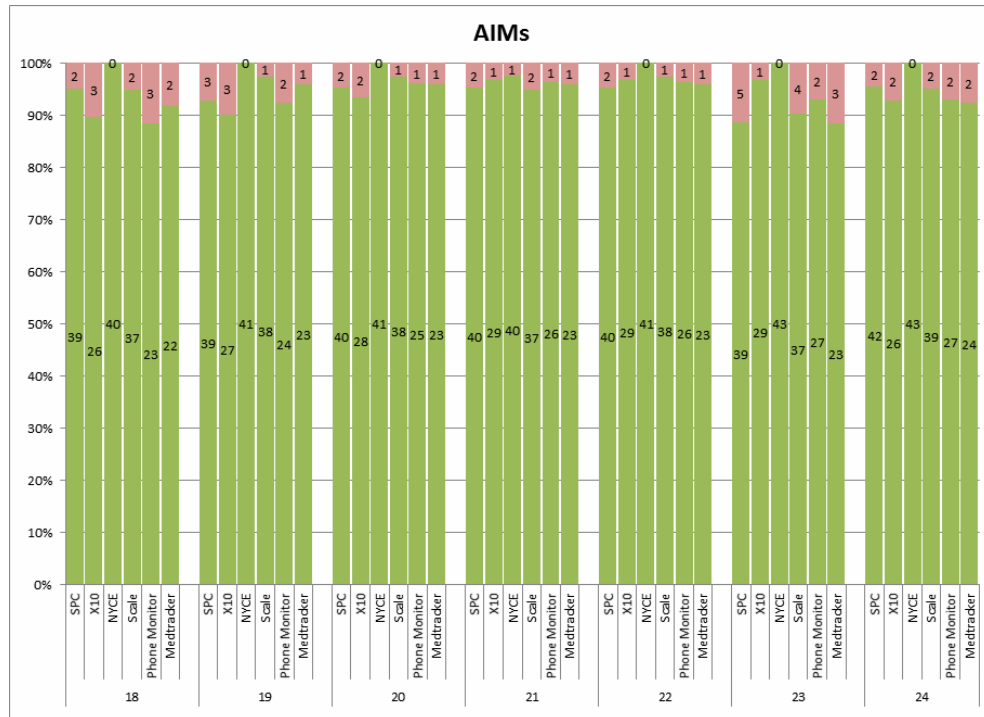
development of analytics in our field.

9) Privacy, Confidentiality and Data Security

Standard institutional practices will be followed as described in the OHSU Information Security and Research Data Resource Guide (http://ozone.ohsu.edu/cc/sec/isg/res_sec.pdf) to maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these procedures. Paper files will be stored in locked filing cabinets in restricted access areas at all study sites. Electronic data is stored on restricted drives on the OHSU, VA and other study site networks. Electronic assessment data will be stored in a web-accessible REDCap database housed on an OHSU secure server, maintained by OCTRI (Oregon Clinical & Translational Research). Electronic survey data will be stored in a web-accessible server at Qualtrics, though copies of this data will be transferred to a secure OHSU server via API call. Other electronic data will be stored on a secure, password protected OHSU server. Access to data is restricted to study personnel. Access to data requires username/password authentication.

Sensor 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 an OHSU research server on a regular basis, but may also be polled on demand. See V1.0 Platform Installation Visit section for more detailed information about device specific data collection and transfer path to OHSU servers.

Approved research staff may access the data for their research participants 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), 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 subject 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 ORCATECH team (see figure above, example from another study).



A core principle of CART is to share the data generated with the research community. In order to do this all data collected from research participants must be de-identified before release to other researchers or the public. Demonstration study sites shall have access to identifiable subject records according to approved IRB policies and procedures via the CART data repository (OHSU IRB#17189). CART sponsors will also have access to study data as required. Authorized CART study personnel shall be able to enter data into the CART password protected database. Data will be made available to the public as expeditiously as possible while respecting the potential need in some cases to have lag time for release of certain data (e.g. young investigators needing first passes at data for primary publication; time needed to file IP disclosures). All users of CART data will consent to a streamlined data use agreement process before obtaining access. Where

relevant, such as in developing sensor-based decision algorithms, investigators using data from the CART database shall provide an overview/documentation of the method(s) used to analyze the data and acknowledge CART in any publications or presentations. The specifications reporting of secondary data analysis may be satisfied through open source publication. All data access and use will be audited with quarterly review by the Data Core and Information Dissemination and Publications committee reporting to the Executive Committee. The data systems are for research only, not intended for clinical use. This will be included in all consent language, e.g., “the data collected or reported is not intended to replace your clinical care”.

10) Risks and Benefits

a) Risks to Subjects

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.

b) Potential Benefits to Subjects

Study participants will receive monetary compensation of \$49 per household (up to \$100 for VA cohort households) that can be used towards maintaining internet connection and as compensation for their time. Participants may find they may 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.