Summary

The ORCATECH Collaborative Aging (in Place) Research Using Technology (CART) program develops and validates an infrastructure for rapid and effective conduct of research utilizing technology to facilitate aging in place (AiP). CART is a unique and innovative research organization to enjoin expert leaders from academia and industry with broad-based experience across multiple fields: gerontology, clinical medicine, health care, psychology, user interaction, systems science, engineering, computer science, technology, data science, business development, ethics and public policy. This CART team works closely together to leverage existing considerable infrastructure, with members from ORCATECH at Oregon Health & Science University, Intel, VA (VISN20), Rush University, Oregon State University, University of Pennsylvania and CREATE (Center for Research and Education on Aging and Technology Enhancement) at University of Miami. As a result, our CART will work rapidly, building on an already-existing system demonstrated as adaptable and sustainable for over a decade. In years 1-3 we will apply a systems development life cycle approach with iterative user-centered design and technology and infrastructure creation. To ensure sustained use and ecological validity of the data, the design is as unobtrusive as possible for research participants, as well as technology agnostic. In year 4 the developed system will be assessed in a Demonstration Project with an original AiP hypothesis fundamental to CART research: *whether the system created provides evidence for sustained independence*. We introduce innovative AiP methods including: a unique Personal Health and Activity Record, combining functionality of a personal health record with ecological momentary assessment capacity; novel use of Bluetooth beacon technology to assess activity of couples and caregivers; assessment of community travel (e.g., driving); and an assessment tool to predict sustainable engagement in future CART research. We rigorously test the AiP hypothesis and these innovations in 360 participants from four diverse senior populations: residents in low income, section 202 housing; veterans in the rural Pacific Northwest; African Americans and other minorities in Chicago (Minority Aging Research Study) and Miami (PRISM study). The secure extensible data system for CART's multidimensional and hierarchical data will accommodate multiple, evolving data ontologies and schema. CART's Data Repository and communications plan will facilitate data and resource sharing of multiple users of different levels of sophistication ensuring the widest impact and dissemination. Several sustainability models will be evaluated to ensure the success of a larger CART phase II effort, resulting in the high-impact research enterprise needed to create evidence for effective assessments and interventions to sustain health and independence for the growing aging population.

Specific Aims: Overall

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 as 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 application 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 this proposal 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 rural 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.

Research Strategy: Overall

1. 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].

1.1 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,

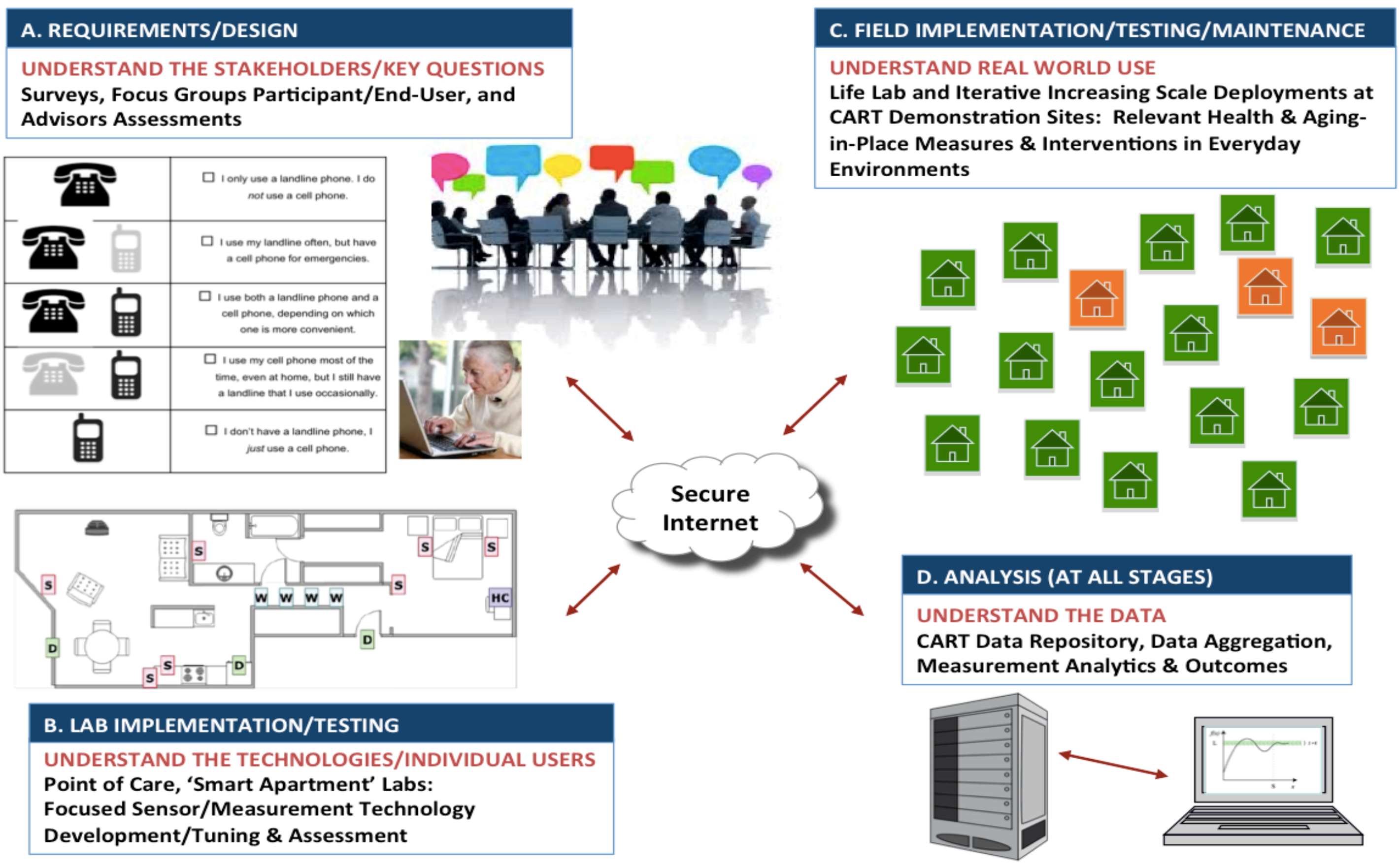

Figure 1. ORCATECH provides four key domains of expertise and functionality necessary for initiating and completing CART system development: A. **REQUIREMENTS / DESIGN** – Expertise for incorporating the input of all key stakeholders; **B. LAB IMPLEMENTATION / TESTING -** Controlled environment laboratories 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.

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.

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 and Atlanta, GA) 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.

1.2 The Senior Independent Living Research (SILvR) Network Initiative. In the process of understanding the needs for creating a wide-scale infrastructure for AiP technology research, the principals of this proposal realized early-on that this effort would require an expanded view garnering the mindshare and involvement of multiple stakeholders with a wide range of expertise. To this end, beginning in 2010 Dr. Kaye and principals at Intel convened a diverse group of key stakeholders from industry, federal agencies, foundations, health care providers, and academic institutions to come together to form the ***Senior Independent Living Research (SILvR) Network Initiative*** or "SNI" (http://silvrnetwork.org). The SNI was designed to develop and sustain a collaborative national research environment and scalable infrastructure to improve the longitudinal study of aging, accelerate innovation and grow the evidence base for healthy aging and independent living.

To achieve the SNI goals the group met regularly, facilitated by funding from Intel, the Robert Wood Johnson Foundation and the National Science Foundation. There were two formal SNI workshops (in December, 2010 and December, 2011), as well as teleconferences and many electronic exchanges. In July, 2012 an organizational meeting was held to solidify the core research group that would actively conduct the first phase of the project. The clear next step emerging from these workshops and related activities was the commitment to move this concept forward in the form of a "mini-SNI" or proof-of–concept (SNI-PoC) study. The PoC had two major goals: (1) Demonstrate (at a small scale) that the proposed SNI principles, organization and governance constitute an effective research environment; and (2) Build evidence that a fully operational and scaled SNI will be able to achieve its future larger intended goal, a 10,000 home network. The SNI workgroup set out 6 aims at the time which are notably aligned with the current CART FOA:

Aim 1: Establish and exercise the basic governance, operational, and policy structures.
Aim 2: Build and coordinate requirements, standards, specifications, and resources.

Aim 3: Identify and qualify equipment, platform, and software.
Aim 4: Design SNI study protocol and recruit a small-scale cohort.
Aim 5: Deploy technologies and execute study protocols.
Aim 6: Compile results and assess study design.

Aims 1-4 addressed key organizational, process and set-up issues. Aims 5-6 involved the actual implementation and operation of the SNI in the field. The Robert Wood Johnson Foundation, NIA (through a supplement to ORCATECH's Roybal Center), and Intel funded pilot work on the first four aims. A summary Operations Handbook and a Requirements and Standards document were created which provide a substantial initial framework for our proposed CART (see Appendix). Cohort demonstration sites were identified to operate for the SNI-PoC deployment (some now engaged for this CART application). These sites were to have a small test cohort of 12 homes each for the SNI-PoC. Importantly, the Foundation for the NIH (FNIH) was charged with raising the funds needed for the remainder of the project, the critical deployment into the field and ongoing data capture over the ensuing year. Unfortunately given the economic climate at the time, the FNIH was not able to raise sufficient funds from outside sources. The NIH deadline set for engagement to raise the necessary funds to conduct the SNI-POC expired in 2013. Nevertheless, since that time the SNI has remained poised to move into action. Ultimately, the SNI created an exceptional groundwork that will provide us with a 'running start' toward achieving the goals of CART.

In addition to the foundational work of ORCATECH and SNI, further key developments have critically informed the field and the eventual work of CART. Of note have been considerable efforts outside the United States. In particular, extensive visioning and roadmap initiatives (with evocative acronyms) have been conducted across the European Union [85-88] including AALIANCE (10), CAPSIL (11), ePAL (12), SENIOR (13) and BRAID (14) [89]. These initiatives created roadmaps for EU research to achieve effective and sustainable solutions to independent living based on in-depth analyses of independent living and information communication technology scenarios developed or under development in the EU, as well as the US and Japan (in the case of CAPSIL, ORCATECH was a member). At the same time, more recent workgroups (e.g., PCAST [90]); the AiP workshop leading to this FOA; [91]and other initiatives (e.g. NSF Smart and Connected Homes) have provided further grist for building the pathway forward in guiding the current CART vision.

While there has been a profusion of guiding documents as well as focused deployments, there have been islands of larger real-world efforts, which have forged ahead to build evidence. These have largely been within the specific domain of telecare, telehealth or telemedicine (each related, but not the same) where the available technologies and response systems have been in development for decades. Notable among these real-world experiments has been the US Department of Veterans Affairs (VA) and their Care Coordination/Home Telehealth Program which has enrolled tens of thousands of veterans [92], the Renewing Health Consortium deployed across nine European countries (21 telemedicine pilots; 7000 patients) [93] and the Whole System Demonstrator RCT of telecare and telehealth completed in the UK [94-96]. These important programs have remotely monitored thousands of patients with multiple chronic medical conditions, facilitated by dedicated home monitoring devices and messaging services supervised by care coordinators. In summary, the results have unfortunately been mixed. This has been borne out by a number of systematic reviews [97-107]. Many issues have been identified as contributing to these inconsistent findings: differences in patient populations, deployed technologies, training, variable outcome measures and analyses, to name a few. Of course these approaches ignore the interplay of 'consumer-directed' health maintenance and the abundance of technologies that may be available outside of mainframe health systems.

Thus, 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.

2. Innovation

We have created for this proposal an innovative structure bringing together expert leaders from academia and industry to guide our CART effort. Working with the co-PIs, the team for this proposal uniquely coalesces the best broad-based experience needed for this research across multiple fields: gerontology, clinical medicine, health care, psychology, user interaction, systems science, engineering, computer science, technology, data science, business development, ethics and public policy. We abide by the principle of being not only technology and disease agnostic, but discipline and institution agnostic as well. We build upon the existing foundation provided not only by our colleagues in the field (e.g., The NIH funded Center for Research and Education on Aging and Technology Enhancement (CREATE)), but already created in particular by the SNI blueprints and existing infrastructure of ORCATECH (Point of Care Lab, Life Laboratory, and data system). This allows our team to work rapidly and build upon a system that already has been shown to be adaptable and sustainable through inevitable technology changes. Using an innovation borrowed from the software and technology industry, the research program development outlined applies a systems development life cycle approach that systematically lends itself to the requisite iterations of technology and infrastructure creation and user-centered design. To ensure sustained use and ecological validity of the data we adhere to the principle of being as unobtrusive as possible in the lives of our research participants. We test an original AiP hypothesis that is a fundamental test of CART research: whether the system created provides evidence for sustained independence. We introduce several innovative AiP methods including novel use of Bluetooth beacon technology to assess interactions of couples and caregivers, assess travel in the community including driving, and create a technology assessment tool specifically for gauging individuals' sustainable engagement in future CART research going forward. We test these innovations in four diverse populations including octogenarians residing in low income, section 202 housing, elderly African Americans and other minorities living in Chicago and Miami, and rural residing veterans in the Pacific Northwest. These cohorts rigorously test the infrastructure, as well as the hypothesis put forward.

3. Approach

Ultimately, as a cooperative agreement and to be responsive to this FOA, accomplishing the goals of CART translates into achieving the specific CART objectives. These are clearly laid out and flow naturally within the four-year timeline of phase I. With this in mind, here we highlight first the overarching guiding principles that we think are critical for the success of all Cores and participants in CART. We then review the approach to achieving the specific aims over time. These are further detailed in the Core and Demonstration Project description sections.

3.1 CART Rules of Engagement. Stemming from our ORCATECH and SILvR Network experience we know that *we must operate within the framework of guiding principles*. These center around principles of openness and the precompetitive space, inclusiveness, technology and disease or condition 'agnosticism', stewardship of available resources, future sustainability and user/patient-centered design. These "CART Rules of Engagement" set the tone for all meetings, collaborative interactions, research protocols and operations, data sharing and dissemination activities. They are further delineated in the **Administrative Core** section.

3.2 Overview of Overall Procedures, Operations and Methodology

3.2.1 Establish and implement the guidance and operations infrastructure for CART. The CART program will start by convening in person the overall team along with the to-be-named federal officials and scientific advisory committee that compose the Steering Committee (SC). From the beginning our SC will engage the PI's and all the core leaders, demonstration site leaders, administrator and COO. Our goal will be to have at least one in-person meeting each year. Realizing the size and positions of the SC we will adopt several mechanisms of facilitated communication including high quality video-conferencing capability, a dedicated e-work site, and a public-facing website.

Because scalability and sustainability are core values, documentation will be key from the start so that any group in the future can take advantage of the knowledge and protocols generated. The team will take advantage of building upon already existing infrastructure to "hit the ground running". Thus the SILvR network created a policy and procedures manual (See Appendix) that our CART proposal builds upon. Sections to be covered for CART: (1) Organization, Roles and Responsibilities (describes the organization of CART and defines the role and responsibilities of each of its parts); (2) Policies (codifies the governing policies of CART; includes handling of intellectual property, publications). (3) System Development Life Cycle Requirements (codifies the means by which systems and technological solutions will be developed, managed and recorded. This includes an emphasis on the functional, non-functional, and user requirements that CART technologies will enable. As part of this effort, specific systems and components that are initially proposed, as well as iteratively integrated later will be specified here); (4) Deployment Manual (covers details for field deployment including personnel training, sample consents); and (5) Data Systems Manual (details system architecture, software specifications; security protocols, rules for access). Through this process we will establish and implement the basic processes needed to develop and sustain the technology-based infrastructure of CART. This includes establishing and coordinating requirements, standards, specifications, and resources for AiP research.

3.2.2 Design and plan the illustrative study protocol for the final Demonstration Project. Ultimately the measure of success will be how effectively the CART system works for building research evidence and answering important AiP questions. The required platform will need to be highly flexible and extensible so as to accommodate the wide range of possible research. However, each individual research question examined needs to be driven by the first principles of specific hypotheses and aims. Thus we propose to develop our Demonstration Project to examine the fundamental AiP hypothesis that ***the multi-domain data generated by the CART system provide the basis for sensitive prediction of loss of independence or need for higher levels of care.*** Given the nature of this FOA, our demonstration project planning will be further guided by the SC and external advisors. The development will be framed within a system development life cycle process spanning two integrated cycles of development with successive versions - CART platform V1.0 and then V2.0 - leading to the final deployment of the system testing the central hypothesis in the Demonstration Project (see Timeline section below for overview of research activity cascade). Four test sites enrolling four distinct cohorts representing potentially challenging life circumstances for CART will work collaboratively over the four years of the program: 1) Octogenarian, low-income, section 202 housing residents (J. Kaye, PI; OHSU, Portland), African American seniors enrolled in the Minority Aging Research Study (L. Barnes, PI; Rush; Chicago), isolated veterans in rural areas enrolled in the Clinical V-Tel (CVT) Veterans telemedicine program (D. Erten-Lyons, PI; VA Northwest VISN 20); and minority older adults (including the oldest old) with variable technology experience from the A Personalized Reminder Information and Social Management System (PRISM) cohort and the general CREATE cohort (S. Czaja, PI, University of Miami).

3.2.3 Design the infrastructure and data systems necessary for the illustrative study protocol needed for the final Demonstration Project. Guided by the CART leadership, the Data and Resource Cores will work together closely to create this overall infrastructure to support research through all phases of the program leading to the Demonstration Project. Proposed project procedures will initially be built upon the current ready-to-go, technology agnostic ORCATECH Life Laboratory infrastructure. At the center of the Life Lab is a platform that has been iteratively developed over the past decade that includes a complete end-to-end (sensors to analytics) system. Importantly, because of the sustained longevity of this system it forms a natural incubator for iterating on new technologies and opportunities as the original system itself has by necessity been systematically incrementally updated as new technical capabilities (e.g. low energy Bluetooth beacons, smart watches, Apache Spark) have come online. As further detailed in the Resource Core this means that the project can be up and running quickly, adapting and evolving as needed. Based on extensive interaction with the leadership and advisors of CART within the first nine months the AiP requirements, which will drive technical specifications, qualifications, metrics and outcomes, will be established and encoded. In parallel, additional data system infrastructure, both software and hardware will be brought on-line and documented. The aggressive time-line will be facilitated by the experience of our industry co-investigators who are accustomed to generating deliverables on quarterly deadlines.

3.2.4 Develop and iteratively refine the infrastructure based on initial design, study requirements, user-testing and iterative system deployments. To enhance incremental improvement of the overall system each site will enroll, deploy and assess our initial CART system in initial waves of 30 homes. The Life Lab team with deep experience in developing AiP technology will lead the cascade of development and deployment beginning with technical preparation as needed and taking advantage of the Point of Care mock apartment and Life Lab itself. Primary anticipated foci of this 1.0 deployment will be ***understanding the unique needs of the use cases, understanding the users (e.g. with interval surveys and focus groups), refining the metrics and problem solving technology integration and remote deployment***. We will incorporate principles of a user-centered design approach. A standard system development life cycle will be employed Without interruption, based on lessons gained during years 1-2 and input from the CART advisory committee, appropriate development, deployment and revisions will be carried forward. Moving from year 2 to 3, new technical capacities (couples interaction measures, out of home activity and overall scalability metrics) will be introduced for evaluation in the next cycle creating a CART Version 2.0 to be deployed and assessed throughout year 3. Again, this will be done sequentially in a cascading manner, adding 30 new homes per site to achieve a total of 60 homes per cohort. Thus by year four, 240 homes with 360 total participants (assuming half may live alone in this selected elderly population) will be consented and ready for the year 4 DP.

3.2.5 The Demonstration Project. CART is a program designed to develop and validate an infrastructure for rapid and effective conduct of future AiP research. As such, it is conceptually not simply a hypothesis driven observational study or intervention. Accordingly, to optimally test the system developed we focus on a hypothesis and aims for the DP that will provide meaningful outcomes data, while at the same time substantiating the integrity of the developed system for future studies. Thus as noted above, we propose to examine the primary hypothesis that the AiP metrics derived from the technologies employed are capable of predicting loss of independence or its risk profile. The aims of the demonstration project are to: 1) Demonstrate 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; and 2) Determine specific instances predicting transitions such as the percentage of days for which medication adherence is poor, time and distance traveled from home are declining, and the number of days in which the resident received in-home care for ADL or IADL assistance is increasing. Given that the DP is four years from now, we anticipate that exploring additional or alternative outcomes may be of interest to the Steering Committee and research community by that time; our system and team are flexible toward examining other outcomes of interest. We propose to run the longitudinal fourth-year DP for 9 months (or longer if there is a desire to transition the followed cohort further into phase II). By design, the iterative process of enrolling volunteers during the development years results in longitudinal data available for at least half of the cohort for up to three years. In building the vital predictive analytics needed for AiP research, longer observation periods are of great value in facilitating the capture of many key life events. The data generated during the development process along with the final DP will result in an unsurpassed set of data for the CART data repository, which will be available to the general research community.

3.3 CART Timeline

An overview of major CART project activities and milestones is summarized below in **Figure 2**.

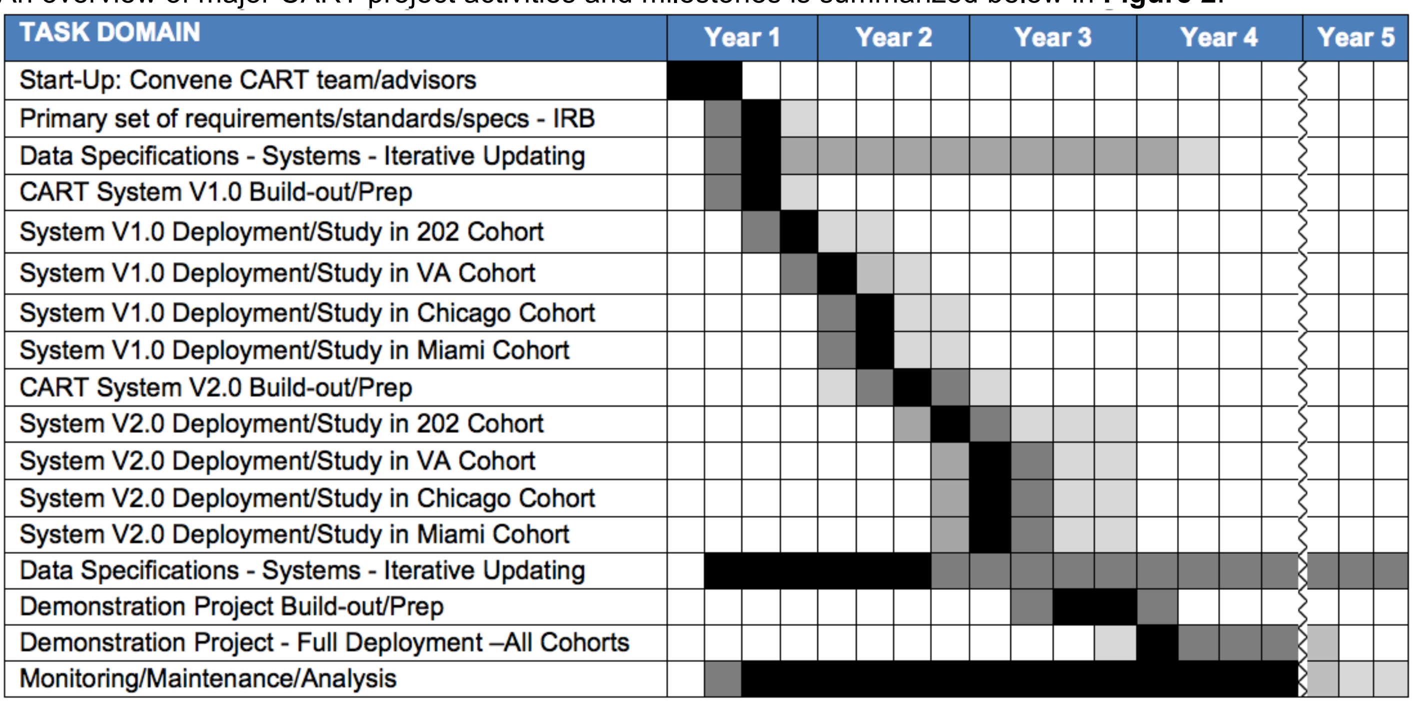

Figure 2. Timeline. Black indicates periods of major work effort to complete milestones or sustain the longitudinal study; gray indicates preparation efforts and/or periods requiring sustained follow-up work; light grey indicates built-in transition periods allowing for adjustment to alternative technologies or methods without major loss of time to next goal. Major milestones are in: Year 1 - completing the start-up phase (e.g., team coalescence, operating manuals, IRB approvals, task allocation, training); V1.0 system completion and pre-pilot "debugging" in Life Lab; Year 2 - complete and subsequent iterative modification of data specifications and data system; Completing V1.0 tests at all sites; CART system V2.0 build-out and prep completed; Year 3 - V2.0 deployment and testing for all cohorts. Year 4 - conduct Demonstration Project testing the CART hypothesis; Year 5 - Phase II begins.

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Summary: Administrative Core

The **Administrative Core** will provide the overall administrative and organizational oversight and management of CART. Central to this function is clarity in purpose and principles from the outset, working hand-in-hand with the Steering Committee and other committees, advisors and stakeholders. Day-to-day activities will focus on responsive coordination with the other Cores (**Data** and **Resources**) and committees, as well as with the four Demonstration Project's development sites to iteratively plan, implement and establish the infrastructure necessary for the final Demonstration Project in year four. **Accordingly, the aims of the Administrative Core are to *collaboratively*:**

1. **Establish the foundational, overarching principles** of operating CART.
2. **Establish and implement basic governance, operational, and policy structures** to ensure seamless functioning of the overall CART initiative and Demonstration Project.
3. **Create an operations infrastructure** that delineates policies, standards, methodologies and procedures coordinating all the operational and logistic elements of CART: the cores, the technologies, software, data and research protocol sharing, communications, fiscal management, handling of ethical issues and potential intellectual property.
4. **Create the scalable demonstration research system**, *recursively* identifying, building and coordinating requirements, standards, specifications, and resources for the AiP research demonstration project; ensure in this process continual iterative appraisal of research methodologies and interim results that is responsive to changing technology and research landscapes.
5. **Ensure at all stages of CART research ongoing evaluation and review** through regular self-assessment and progress reporting.
6. **Facilitate public-private partnerships for investment in sustainable CART infrastructure.**

Specific Aims: Administrative Core

This CART proposal details the process and methods we will use to build a sustainable infrastructure for the Aging in Place (AiP) research community. The ultimate goal is to be able to scale our infrastructure to a 10,000 home research community. As such, CART needs to be generalizable (agnostic to disease or aging condition, as well as technology), sharable, readily deployable and ultimately sustainable. The FOA provides a basic framework for achieving this vision, the result of much forethought (workshops, expert input, literature reviews). It clearly recognizes the central position of the **Administrative Core** in organizing, implementing and maintaining CART. The **Administrative Core** will be a central element of our proposed CART playing a critical role in the provision of careful oversight, day-to-day management and continuous review of CART's activities. We base our approach to the structure and function of this core on our own experience both in academic and industry settings, creating a complementary marriage of the two. Thus we build upon the ORCATECH experience over the past decade in deploying and maintaining AiP technologies in over 400 seniors' homes continuously for up to seven years in multiple environments. We also draw upon experience in collaborating with national scalable projects to first grow mindshare and stimulate collaboration of diverse investigators and sites and then to recursively pilot and build infrastructure to support those sites' ongoing work. For example, in the Home-Based Assessment study conducted as part of the Alzheimer's Disease Cooperative Study, we designed, trained, deployed and maintained technologies in sites located in 26 US cities, following 200 seniors for up to four years in this project [1, 2]. In the SILvR network collaboration, ORCATECH and Intel engaged over 50 public and private entities in a consensus building process leading to a scalable demonstration project protocol (http://silvrnetwork.org/welcome). We draw heavily upon this experience here. We also draw on the experience of our team such as Dr. Czaja's extensive experience in directing the NIA supported Center for Research and Education on Aging and Technology Experience (CREATE). Over the past 16 years CREATE has successfully built collaborations with industry and the community, and engaged in multi-site projects. A fundamental focus of CREATE is on technology systems for older adults. The co-investigators from Intel in our CART proposal have routinely taken projects from requirements to scaled products as part of their fundamental work responsibility. This has been achieved in the commercial sector, but and also in collaboration with academic research such as with ORCATECH and the development of the Technology Research for Independent Living Center (TRIL) in Ireland. The latter was a $30M co-investment by Intel with the Irish government in a collaboration that included over 60 principal investigators across Intel, University College Dublin, Trinity College Dublin and St. James Hospital. As part of TRIL several technical solutions were developed end-to-end by researchers at Intel and the Irish academic consortium including the modular shimmer™ platform for integrating wearable sensing technologies and the QTUG™ tool for assessment of mobility impairment, frailty and falls risk.

Based upon this collective experience, the **Administrative Core** will provide the overall administrative and organizational oversight and management of CART. Central to this function is clarity in purpose and principles from the outset, working hand-in-hand with the Steering Committee and other committees, advisors and stakeholders. Day-to-day activities will focus on responsive coordination with the other Cores (**Data** and **Resources**) and committees, as well as with the four Demonstration project's development sites to iteratively plan, implement and establish the infrastructure necessary for the final Demonstration Project in year four. **Accordingly, the aims of the Administrative Core are to *collaboratively*:**

1. **Establish the foundational, overarching principles** of operating CART.
2. **Establish and implement basic governance, operational, and policy structures** to ensure seamless functioning of the overall CART initiative and Demonstration Project.
3. **Create an operations infrastructure** that delineates policies, standards, methodologies and procedures coordinating all the operational and logistic elements of CART: the cores, the technologies, software, data and research protocol sharing, communications, fiscal management, handling of ethical issues and potential intellectual property.
4. **Create the scalable demonstration research system**, *recursively* identifying, building and coordinating requirements, standards, specifications, and resources for the AiP research demonstration project; ensure in this process continual iterative appraisal of research methodologies and interim results that is responsive to changing technology and research landscapes.
5. **Ensure at all stages of CART research ongoing evaluation and review** through regular self-assessment and progress reporting.
6. **Facilitate public-private partnerships for investment in sustainable CART infrastructure.**

Research Strategy: Administrative Core

1. Significance

The overall significance of CART will ultimately be gauged by our success in developing and validating an effective infrastructure facilitating AiP research at scale. The key elements to achieving this goal are wide-ranging including: developing an efficient organizational structure; operational procedures; technology (identification, specification, setup, deployment, maintenance, replacement); human factors assessments; data systems/software design and implementation; data management and data analytics. Our CART proposal has four diverse collaborating development sites that will support the work leading to, as well as conducting the final prototypical Demonstration Project in year four. These sites are chosen not only for the exceptional scientific leadership and expertise of the principals and teams of these sites, but also for the richly informed insight to be provided by each site's unique and diverse pool of research participants.

In addition to the local community participants, the overall process needs to be informed by the input of many additional stakeholders at many levels (e.g. NIH, ONC, VA, FDA, CMS, industry, public policy and advocacy groups, community organizations, and many others). Further, guidance by specialists from the scientific community represented by the Scientific Advisory Panel and other ad hoc advisors must be incorporated. Thus, the **Administrative Core**, perhaps even more than in most other projects, has an extensive, mission-critical role in establishing and ensuring all the CART parts function seamlessly as an integrated whole. Having participated in a number of collaborative multidisciplinary technology and aging consortia, we know that there will be hard 'trade-off' decisions that will need to be made with champions on both sides of reasoned positions, e.g. "wait, there is a new smartphone that solves that problem coming out in the next quarter" verses "lets go with the established, usable, 'today' technology". In addition to best practices and technologies adopted, less promising ideas and proposals need to be effectively and efficiently filtered as well with the **Administrative Core** being central in its role as the facilitating crucible for this kind of decision-making.

Finally, the Administrative Core will ensure that in creating a built-to-last blueprint it is a given that documentation and sharing with the larger community the common elements needed to conduct the research (e.g., user requirements, software specifications, deployment manuals, etc.) is routine. We also incorporate and emphasize that the decision-making used in the recursive development process itself be documented and reviewed in an open and outward-facing process. All documents are intended for wide sharing and dissemination via an effective public website, social media and annual meetings. Data will reside in a secure but sharable Data Repository with links to national data repositories such as the National Archive of Computerized Data on Aging (NACDA; http://www.icpsr.umich.edu/icpsrweb/NACDA/; see support letter), and the Integrated Analysis of Longitudinal Studies of Aging (IALSA; http://www.ialsa.org/) collaborative. Dr. Kaye is a Co-PI of IALSA, an NIA program project to facilitate aging data harmonization and sharing.

2. Innovation

This proposal is innovative in a number of important ways. **First**, because of our considerable prior foundational work accomplished leading up to this CART proposal the Administrative Core is unusually positioned to quickly move into action and efficiently establish and engage all necessary operational elements. **Second,** although the FOA proscribes much of the organization and operational activities of CART, within this framework we have instituted several original approaches to conducting the program. An example is our innovative public-private collaboration. This begins with the leadership and extends through the cores and sites. **Third,** the co-PI's represent a unique leadership structure that was successfully pioneered with the ORCATECH Roybal Center. They have worked together for many years within the same problem space addressed by this proposal. **Fourth,** this proposal is based on a team science approach and engages experienced multidisciplinary experts in public and academic health and technology research settings embodied by our university-based and VA collaborators**. Fifth**, the make-up of our research team allows us to draw on the resources of other well established NIH funded programs and Centers such as CREATE and the Minority Aging Research Study. **Sixth**, it is clear that to be successful in building a future-forward, scalable technology CART infrastructure, meaningful involvement of industry is also necessary. Intel brings an exceptional breadth of connections to the technology world at large, as well as deep experience in technology creation across the entire development cycle. The team will iteratively develop its technology infrastructure using a systems development life-cycle user centered design process built upon existing ORCATECH infrastructure. **Seventh,** several innovative committees are proposed to facilitate the research process. These include committees dedicated to Ethics and Policy, and External Relations, especially important for working with other industry entities and health systems where privacy, security and intellectual property must be evaluated. External Relations will be especially important for our proposed novel public-private partnerships to sustain investment in CART AiP research with new industries such as independent living and Pharma focused companies. Other committees focus on Communications (especially electronic) and Information Dissemination. These committees emphasize the degree to which we place high value on accountability and information exchange and dissemination. **Eighth**, we propose innovative sustainability models such as collaborative efforts with the Foundation for NIH and industry and creation of a not-for-profit entity that would be capable of licensing potential CART derived IP in such a way that the revenue streams could be used to sustain CART.

3. Approach

3.1 Guiding Principles and Definitions

AiP Research Framework. Effective operation of the CART research enterprise needs to be informed by delineating the boundaries of the problem space. The topic of "Aging in Place" and maintaining independence cuts across very wide areas of gerontology, behavioral science and health research. When technology is brought into this research arena, there is a tendency to be drawn first to the technologies rather than to the characteristics of the intended user, the potential value of the technology for these users, the intended use of the technology (e.g., tasks that the technology can support), or the context in which the technology will be used. With this in mind, we think that CART needs to keep foremost in mind a focus on the known factors that foster AiP or independence. Our work [3] and others [4-7] have consistently identified a number of significant factors that lead to loss of independence or need for higher levels of care: age, cognitive decline, functional impairment, medical illness, emotional infirmity, social isolation and low activity. Many of these factors are modifiable and they are often closely inter-related. Thus the framework and focus of the development, evaluation and deployment of technology needs to be centered on how the technologies deliver added value to assessment and/or intervention in these areas already demonstrated to be most critical for AiP. In this regard, we adopt a user-centered/patient-centered philosophy in our research activities.

A very practical summary of this framework has been proposed [8] which we adopt as a useful starting point for specifying a technology framework for AiP that focuses on how technology fits into the most important domains of life function and quality of life. In this conceptualization there are five basic life domains (physical and mental health, mobility, social engagement, safety, everyday activities and leisure) and three major technology domains (Monitoring/measurement - of the person and environment; Diagnosis/screening; and Treatment/intervention - including compensation, prevention, enhancement). This taxonomy may be further subdivided or modified as there are many schemas both for life-wellness domains [9] and technology [10, 11]. Thus, we anticipate that *the Steering Committee and CART team will further shape this framework as the project moves forward, which in turn will represent a major contribution to the literature.*

Scalability. The FOA points to the goal of "the likelihood that (a) scaled up version (of the CART infrastructure) (Phase II) will be deployable for continuous operations in up to 10,000 homes." This is a worthy goal, although we believe it will be important to further consider scalability in more detail on several levels. The technologies to be deployed inherently allow data to be captured at different levels of abstraction and connectivity. Thus 10,000 homes could be considered as 10,000 couple dyads (or 20,000 individuals) where large amounts of direct, detailed life-activity data are acquired. However, if these homes are connected and capturing additional on-line or mobile data from their care network, the number of individuals can considerably multiply and scale further. Ultimately, *the research question is key and should determine the sampling strategy*. Studies of genome-based susceptibility to frailty and loss of independence could require well in excess of 10,000 homes (or individuals). On the other hand, some research questions may require many fewer homes because the effect sizes generated from highly frequent continuous sensed data allow for much more precise estimates of trajectories of change at the intra-individual level [12]. Thus a clinical trial or intervention may require a tenth of the sample needed in current study designs by employing these continuous data capture systems. We thus take scalability to mean being able to build out and replicate the basic CART system to thousands of instances which can incorporate the most important use cases and outcomes, for example real-world studies that examine critical outcomes such as reduced hospitalizations, care transitions, improved quality of life, delayed nursing home placement, etc. Further, although it may be that there is a single large Phase II, 10,000 home study in the future, it is also important to consider the hundreds of ongoing or planned studies (e.g., http://www.ialsa.org/). We plan to provide benefit to and complement these many studies by intercalating CART technology if possible into their existing or planned protocols. Finally, scaling should be considered as not just external, but in the internal environment as well. Technologies and software systems must accommodate the growth of multiple types of devices and sensors that can be deployed in personal space.

Frameworks for Iteratively Developing and Evaluating AiP Research Technology. Equally important to framing the overall CART AiP research focus is delineating the processes for developing and evaluating AiP research technology. As noted we will adopt a user-centered design approach and thus for CART, among the most important considerations is user input at all levels of research. This process may be best conceptualized as a continuum [8, 13] beginning with an analysis of end-user characteristics and needs and theoretical task analyses of the technology, task and environmental demands, developing/testing prototypes and progressing to laboratory-based and then field-focused studies. A number of evaluation design methodologies can be employed iteratively along the way, first in early phases (e.g., story boarding, focus groups, prototype testing, "Wizard of Oz" studies) and then in later, larger field studies (e.g., randomized trials, comparative effectiveness studies, interrupted time series). At each step many measurement strategies may be employed depending on the stage of development and the ultimate use cases anticipated (e.g., ease of use, acceptability, user satisfaction, efficiency, reliability, ground truth validation, quality of life, needs for care, etc.).

Table 1 - CART 'Rules of Engagement'

Principle	Meaning and Intent
Precompetitive Environment	*All stakeholders welcome. A place where common approaches, standards, etc. lift all boats. Members and participants to include government, academia, foundations, communities, and industry.*
Open	*Data with appropriate consent and security measures will be open to the research community and public; not primarily designed to be an engine for the development of intellectual property, technology, or products per se, but pathways for commercialization are important to be kept in mind and available.*
Focus on Senior Independent Living Research	*Understanding aging in seniors and the process, tools, and behaviors that enable independent living; user-centered; not designed to simply focus on a particular disease or condition.*
Multidimensional and Multidisciplinary	*Requires inclusion of health, behavioral, social, biological, clinical, genetic, economic, environmental, caregiver, policy, and resource effects and their interactions. Not, for example, setting up for research in isolation such as just telemedicine, a single device, app use, health coaching (although these are all appropriate in the proper context).*
Unobtrusive	*"Ambient" technologies are preferred: whenever possible systems and technologies developed and deployed result in the minimum amount of disruption in the daily life of the user.*
Technology, Platform, Solution Agnostic	*Will not promote a specific technology, product or service.*
Private and Secure	*Personal data privacy and security are foremost considerations in all stages of the research*
Holistic	*Consider all major constituencies, their influences, and their interactions: senior participants, clinicians, and informal caregivers and their associated resources, location, and technical capabilities.*
Leverage existing investments/resources	*First and subsequent iterations to build extensively on existing funded research; developed technologies and established experience; do not reinvent the wheel.*
Built to last	*Sustained operation necessary to achieve the vision and demonstrate the greatest value.*

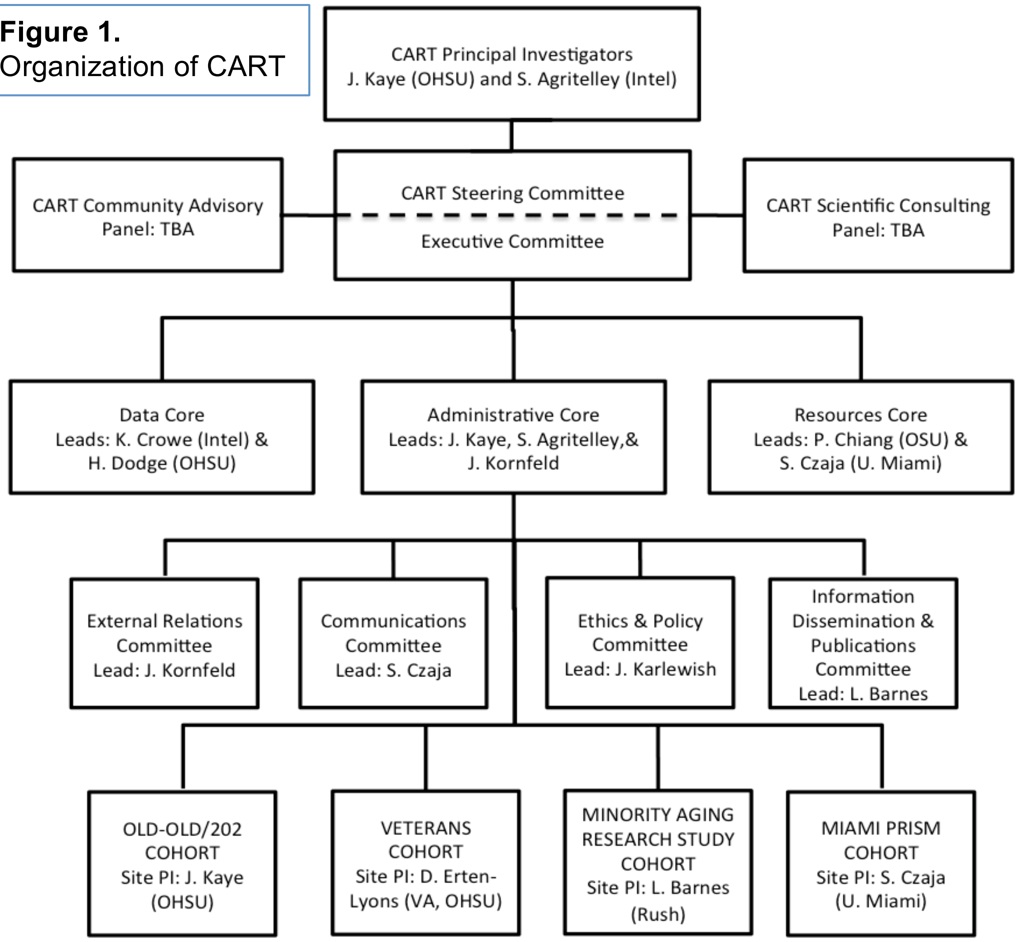
To further facilitate iterative development a standard development process framework is needed. We adopt the widely used industry standard approach for technology and software development defined by the **System Development Life-Cycle** (SDLC). Common SDLC phases include: Vision and Planning; Analysis and Design; Development and Testing, Deployment and Validation, and Maintenance. Not every phase of the SDLC may equally apply, i.e., much of the time and effort spent in Analysis and Design phases may be reduced by choices made in the Planning phase to scale out an existing tested system from Life Lab and/or other collaborators. Further details of the SDLC process are described below and in the **Resource Core** Section.

CART 'Rules of Engagement'. Stemming from our ORCATECH and SILvR Network experience we believe we must operate within the framework of ten guiding principles (**Table 1**). These "Rules of Engagement" set the tone for all CART interactions: meetings, collaborative exchanges, research protocols, data sharing and dissemination activities.

3.2 Organization, Governance, Operations, and Policy Structures

The **Administrative Core** (AC) provides the central managerial and guiding framework for the entire CART research enterprise. Accordingly, the AC's first action will be to establish the basic organization, governance, operations and policy structures for successful long-term operation of CART. As noted, we will build on our existing infrastructures, experiences and protocols. The AC will be responsible for fiscal management (grant and contract administration, purchasing, budget tracking) and personnel management. Day-to-day operations including scheduling key regular meetings, reviews and ensuring timely reporting functions will also be under the purview of the CAC. In addition, the AC will be responsible for ensuring communication and cohesion among the various entities of CART including the 4 cohort sites, and with other entities such as community organizations and other key stakeholders (e.g., NIH). Although much of the basic structure and function of CART is proscribed by the FOA with required cores, committees and processes, we will substantially build on this framework to enhance the function of each of its units and personnel. The overall organization of CART is outlined in **Figure 1**.

Figure 1.
Organization of CART



3.2.1 Leadership. CART is inherently a multidisciplinary, multicomponent research program. It thus requires substantial knowledge and expertise across a broad range of disciplines and competencies: gerontology, behavioral science, healthcare, user-centered design/usability testing, data science, computer science, engineering, large-scale project management, and industrial-level process improvement. In order to most effectively lead CART co-principal investigators, Jeffrey Kaye (OHSU; Layton Professor of Neurology & Biomedical Engineering, Director of ORCATECH) and Stephen Agritelley (Intel; Director, Health Strategy and Solutions) –will serve as the overall leaders of CART. This unique combination of leadership brings together expertise from academia and industry combining major knowledge and experience across the many domains needed to most successfully realize the vision of CART.

Dr. Kaye has spent over 25 years in human aging research as PI of a number of multidisciplinary longitudinal aging studies funded by the VA (the Oregon Brain Aging Study now in its 24th year), as well as NIH (e.g., Bioengineering Research Partnership, Intelligent Systems for Assessing Aging Change ISAAC cohort, AG024059; Ambient Independence Measures for Guiding Care Transitions, AIMS cohort, AG042191) and other agencies. This research has focused on why some people remain healthy and functional into very advanced ("oldest old") age while others lose their health and independence earlier. In the process of conducting this research using the traditional tools of clinical research (self report scales, psychometric tests, physiologic assessment, genetics, imaging, etc.) it became clear that these tools had major limitations in that they can provide only episodic, non-optimized data that often lacks ecological validity. Thus, beginning over a decade ago we began to develop a systems approach that takes the assessment into the life spaces of people in real time to more objectively assess change and develop effective strategies to maintain health and independence. The basic tools for doing this were based on advances in pervasive computing and sensing, wireless communications and ‘big data’ analytics. This early work was developed with major collaboration with partners at Intel beginning in 2001. This work rapidly evolved leading in 2004 to the establishment of ORCATECH as a Roybal center (P30AG024978) and the introduction of the Life Laboratory as a sustained, 100+ community-wide volunteer cohort designed to facilitate home-based research using technology to transform understanding about aging independently. Subsequently in a formal agreement with Intel, the “Behavioral Assessment and Interventions Commons” (BAIC) was established (2006) as a research commons with OHSU-ORCATECH and the TRIL consortium (Technology Research for Independent Living, a research consortium combining Intel personnel and researchers from Irish universities and hospitals). Importantly Dr. Kaye also has clinical experience with older adult populations so he is uniquely positioned to understand the issues of AiP. Stephen Agritelley was and continues to be a major collaborator of Dr. Kaye’s and as a result of this ongoing work brings unique expertise in integrating teams of ethnographers, designers and engineers with expertise in aging, personal health, healthcare, social media, behavioral change, sensor networks, field testing, and all aspects of user-centered design. Given his experience as a Director of Product Incubation and Prototyping at Intel, as well as a healthcare innovation lab at Intel he is particularly well positioned to facilitate the development and translation of research into actionable, functioning “products”. This is key for the scalability of CART.

3.2.2 Oversight: Steering Committee, Scientific Consulting Panel, and other committees.
The PI’s of CART will work integrally with representatives from the named key federal agencies (NIH, VA, ONC, CMS, NSF and FDA), the Core Leaders (**Administration, Data** and **Resources**) and our CART Chief External Engagement Officer (CEEO; non-voting member, described further below in the External Relations section) to form the CART Steering Committee. The **Steering Committee,** which will serve as the main governing board for CART, will establish further advisory committees or subcommittees once the core ensemble of leadership is convened. This includes the critical **Scientific Consulting Panel** to be named post award as per the FOA. A **Community Advisory Panel** will also be constituted post award to include input from the aging community and relevant representative advocacy groups. In addition, based on our vast experience with this type of endeavor, we propose several committees to best meet the goals of CART: (1) **External Relations**; (2) **Communications**; (3) **Ethics and Policy**; and (4) **Information Dissemination and Publications**. These committees are further described in sections below. We emphasize that the leadership of our proposal anticipates working with a number of advisors with whom we already have strong working relationships, from major university laboratories, as well as industry, health care and policy sectors. Indeed, we have discussed with several of these potential members (without formal commitment as some may be asked to serve on the Scientific Consulting Panel) that they become not only advisors, but direct contributors to our initial CART group and anticipate that through supplemental or other funding, these excellent scientists may be engaged in CART research in subsequent years. Further, we anticipate that we will inform our work best by engaging various relevant constituencies in the public advocacy and policy arenas. To this end, we have taken the initiative to reach out to organizations such as AARP, the CDC Healthy Brain Research Network of the CDC Prevention Research Centers Program, LeadingAge, and the Coalition Against Major Disease (see support letters) representing important knowledge domains (e.g., retirement living, healthy aging, assisted and home care, caregiving, novel outcome measures for FDA) and needed perspectives. To ensure timely optimal function of CART, an **Executive Committee** (a subgroup of the Steering Committee) composed of the NIH program leader, the co-PI’s, Core leaders and the four Demonstration Project development site PI’s (see below) will form a day-to-day operations group meeting weekly. This will be conducted via teleconference as needed.

3.2.3 Cores and CART Demonstration Project Development Sites. In addition to the **Administrative Core**, the other requisite cores, (**Resource** and **Data**) will be tightly linked not only by Steering Committee membership, but also by the fact that so much content and work of each core is interdependent. Specific detail of the Core’s research strategies and interactions are provided in the sections describing each core. Here we highlight the leadership of the cores who will regularly interact as members of the Executive Committee, as well as within their core and as appropriate, with the committees. Of note, the Cores are intentionally *co-led* by highly accomplished researchers who complement each other across cores. The **Resource Core** is co-led by Drs. Patrick Chiang and Sara J. Czaja. Dr. Chiang is Associate Professor of Electrical Engineering and

Computer Science and Director of the VLSI (Very Large Scale Systems) Laboratories at Oregon State University and Fudan University, China. Dr. Chiang has international expertise in several critical areas for this project including technical expertise in SDLC-based integration of health devices and systems, technical challenges (especially electronics miniaturization, form factors and power management) and scaled deployment. He currently leads the engineering team for a 600-person USDA obesity prevention study using wrist-worn devices (USDA-NIFA AFRI Award No. 2013-67001-20418). The PI (JK) has collaborated with his team for many years through ORCATECH (NSF award #1118017, Enabling Technologies for Assessing and Assisting Independent Living, [14, 15] . Dr. Sara Czaja is Leonard H Miller Professor of Psychiatry and Behavioral Science at the University of Miami Miller School of Medicine and the Scientific Director of the Center on Aging. She holds secondary appointments in the Departments of Psychology and Industrial Engineering., She is also the Director of CREATE (Center on Research and Education for Aging and Technology Enhancement). CREATE, funded by NIA, involves collaboration with the Georgia Institute of Technology and Florida State University and focuses on making technology more accessible, useful, and usable for older adults. She is internationally recognized for her work in developing strategies to improve the quality of life for older adults, applying expertise in aging and cognition, caregiving, human computer interaction, training, and functional assessment. These two Core leaders combine extraordinary complementary skills and expertise in engineering, gerontology, pervasive sensor technology, technology user needs and assessment, usability testing and in set-up and deployment of community-based research programs using technology.

The **Data Core** is co-led by Drs. Kathleen Crowe, Director of Data Science for Big Data Solutions at Intel and Hiroko Dodge, Associate Professor of Neurology at OHSU and University of Michigan. Dr. Crowe's early training was in applied mathematics. She began her career in academics as a mathematics professor and then moved to positions in software development (for Fannie Mae), Lead Scientist for FICO (the credit risk software company), and Director of Analytics at Opera Solutions (the big data analytics company focused on predictive modeling and large-scale data management especially for the health care and financial sectors), prior to joining Intel. At Intel Dr. Crowe develops the analytics solutions and capabilities of the Data Center Group by defining software requirements, and directing multiple analytics engagements including integrating a precision medicine program into a health system [16]. Dr. Dodge is an internationally recognized gerontologist and statistician. She is Associate Professor of Neurology at OHSU as well as at University of Michigan. She directs the Data Core of the NIA - Layton Aging & Alzheimer's Disease Center (which has provided the clinical database for ORCATECH). In this latter role, she oversees the direction and coordination of all aspects of data handling from entry to analysis. Her deep expertise includes study of longitudinal trajectories of activities of daily living and cognitive function over time, cross-national comparisons and predictive values of neuropsychological tests, novel cognitive and behavioral measures, age associated decline in leisure and social activities, and clinical trials. She recently completed the first RCT designed to increase the 'dose' of social engagement using home-based monitoring and technology to assess and encourage conversational interaction in at-risk seniors [17-19]. As such, she has an exceptional understanding of the strengths and limitations of remotely acquired in-home sensed data and technologies in the setting of older adults.

To most effectively develop the final Demonstration Project, four CART **Demonstration Project Development Sites** have been enjoined to immediately begin working collaboratively at CART's inception. The sites were strategically chosen for their expertise in aging research and to represent constituencies and environments that will present unique challenges with respect to meeting the goal of scalability. Thus these sites will stringently test and "harden" our infrastructure. These sites also provide access to diverse the populations that are at highest risk for losing independence and thus are most challenged to sustain AiP: octogenarians, those isolated or living alone, those of low socioeconomic status, ethnic minorities, and those with multiple chronic medical conditions. These four cohorts, sites and their leadership are further described below (**section 3.4.1**) in the summary of the development leading up to the Demonstration Project.

3.3 Procedures, Operations and Methodology

3.3.1 Meetings. The CART program will start by convening as soon as possible an in person meeting of the overall team to include the Steering Committee (SC) and the to-be-named federal officials and Scientific Consulting Panel members or ad hoc advisors. This will be a focused day and a half meeting to thoroughly review the current state of CART and delineate concrete action plans. Our SC will engage the PI's and all core leaders, demonstration site leaders, administrator and CEEO at CART's inception. We will hold two in-person meetings of the SC each year preferably in Bethesda or sites that maximize the efficiency (cost, travel, attendance) of the entire SC and other important CART members. Where appropriate, (e.g., if a featured research session on CART is being presented) we propose to engage the team on an ad hoc basis and at meeting venues where many key members may be in attendance (e.g. GSA). The Executive Committee will meet weekly using a tele-video-conference format given the geographic diversity of the CART leadership.

3.3.2 Communications. The leadership of CART is composed of some of the most prominent scientists and program leaders in the AiP, health, gerontology, data science and technology fields. Although they are all fully committed to CART, it is obvious that everyone may not be able to attend all meetings in person because of occasional professional or personal schedule conflicts. In acknowledging this fact, we will adopt several mechanisms of facilitated communication including high quality video-conferencing capability for all meetings, a dedicated password-protected e-work site or "wiki", and a secure website. For all meetings and conferences an administrative assistant will be present to record minutes; minutes will highlight action items. These steps will provide an efficient mechanism for communicating and recording all the evolving artifacts of the research (e.g., meeting agendas, minutes, action items, forms, specifications, summary reports, presentations, etc.) across the entire organizational hierarchy.

Communication with the wider research community and public is also vitally important, and will be a major focus of the CART website. We have reserved the domain name of "aipresearch.org"; if not awarded we will gladly transfer these domains if desired to the eventual awardee. CART web presence will be developed with the input of NIH media staff and other partners. This will include curated social media interfaces to maximize dissemination of CART experience and resources. All communications work will be overseen by a **Communications Committee** led by a communications/webmaster and Dr. Czaja (**Resource Core** leader) who is an expert in website design and communication. The **Communications Committee** will have oversight of the development and maintenance of the CART website and media presence. To maximize the visibility of CART, the CART website will be linked to the websites of the other key leaders (e.g., CREATE). The Communications Committee will track the impact of CART information dissemination (e.g. visitors to website, number of citations, etc.). This Committee will report monthly and on an as needed basis to the Executive Committee. In addition, it is anticipated that the website and CART email address will be important ports of entry for potential user-friendly data sharing pointing to a variety of data resources (raw or processed data, metadata, and visualization tools). This later topic is discussed further in the **Resource** and **Data Core** sections.

3.3.3 Ethics and Policy Development. Without question, the CART leadership will be engaged in an ongoing process covering important policies and procedures that will require the input of the entire SC and other advisors who will be engaged. We believe that a committee that oversees these areas – the Ethics and Policies – will best facilitate development and oversight of these critical areas. Dr. Jason Karlewish a highly respected gerontologist, public policy and ethics expert at the University of Pennsylvania will chair the **Ethics and Policy committee**. He will be joined on the committee by Dr. Katherine Wild (an expert in technology use and adoption by older adults) and Dr. Lisa Barnes (PI of the Minority Aging Research Study, see below). Here we outline some starting points and principles for this process that we believe will facilitate the development of more detailed formal policies. Among the most important areas that must be covered are: human subjects, privacy, data sharing and data systems, intellectual property and conflicts of interest, and publications. Several of these areas overlap in particular with the work of other proposed committees (see below, the **External Relations** and the **Information Dissemination and Publications committees**; these committees by necessity will work in concert.

Protection of Human Subjects. Our policy with regard to human research volunteers is that we will require that all CART research is governed by the policies and procedures of a legally constituted Institutional Review Board (IRB) according to applicable State and Federal requirements for each participating location. Although we entirely subscribe to the desire to operate within the framework of a single IRB we anticipate, initially at least, that the site principal investigators will be responsible for obtaining local IRB approval/renewal during the study and forwarding these approvals on to the **Administrative Core**. At the OHSU site there is a common review process for the Portland VA and university protocols that adheres to the unified IRB principal. In all cases any amendments to a protocol must first be reviewed by the **Administrative Core** and Executive Committee before forwarding on to the IRB for their approval. All human subjects or a legally authorized representative must sign written (or approved electronic or telephone) consent before participating in any CART research. Acquisition of informed consent will be documented in the participant's records, as required by

21 CFR Part 312.62, and the informed consent form signed and dated by the participant and by the person who conducted the informed consent discussion. The original signed informed consent form will be retained and a copy provided to the participant or legally authorized representative. In the process of participating in this research all participants' anonymity and privacy must be maintained. Policies with regard to privacy and security of data will be codified in close collaboration in particular with the **Data Core**.

Data, Data Systems and Data Sharing. 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. 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". Data security is further addressed in the Data Core.

Intellectual Property (IP). Just as medications and medical devices cannot be successfully brought to the public at scale without industry's engagement, CART developed technologies and systems will benefit greatly from the industrial design, research and development and end-productization knowhow of technology-focused industries. We tacitly acknowledge this fact by calling on our existing collaborations and engagements with industry (e.g. Intel, Sharp, Phillips, Amazon, GE, Vigil, Microsoft, NYCE, Elite Care, and many others; see support letters). These relationships will facilitate navigating the natural tension and potential barriers to development we are keenly aware of that exist for academic researchers, in university business development offices, and in the R & D counterparts of industry. Emblematic of this challenge we note for example that the FOA appropriately challenges the research community to make available the software source code and documentation from the CART system to facilitate continuation to larger scale development. At the same time, "The terms of software availability should permit the commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages". This will require significant further development with CART partners with special expertise in intellectual property (IP) agreements. We propose that the initial nexus of this discussion reside in our proposed **External Relations Committee** in collaboration with the **Ethics and Policy Committee** which will oversee developing standard CART memorandums of understanding, confidential disclosure agreements, conflicts of interest declarations, material transfer agreements and other critical relational policies and procedures. Judith Kornfeld will lead this effort as Chief External Engagement Officer (CEEO) for CART. She has been the Chief Operations and Business Officer for ORCATECH for the past three years, responsible in that role for similar operations, identifying and developing potential university-industry collaborations and navigating IP issues. Prior to joining ORCATECH and OHSU she held international positions as Vice President for Business Development in Pharma and the medical device industry (TransPharma Medical, Notal Vision, Impulse Dynamics). Her experience will ensure our CART program will be able to rapidly and effectively engage the private sector for appropriate and vital input. Ms. Kornfeld will work with the Steering Committee to further develop novel policies and procedures to take advantage of these relationships. At this point in time, *we believe that any negotiations on IP rights created in whole or in part under CART, if applicable and related to commercialization activities, must be conducted in a manner that furthers the mission of CART.* Participation in CART will not affect partners' ownership rights to pre-existing IP or inventions made by its employees. Ownership of inventions made by any partner will be determined by U.S. applicable patent law. In the spirit of sharing resources and data within the CART community, each partner is encouraged to manage IP in a manner which allows sharing of technology within CART and the broader research community for research purposes while at the same time protects those inventions, which may benefit from patent protection to facilitate downstream development.
Publications. The intent of the publication policy that we propose is to provide guidance on how CART and its systems and data should be acknowledged in publications. This provides a mechanism for tracking the impact

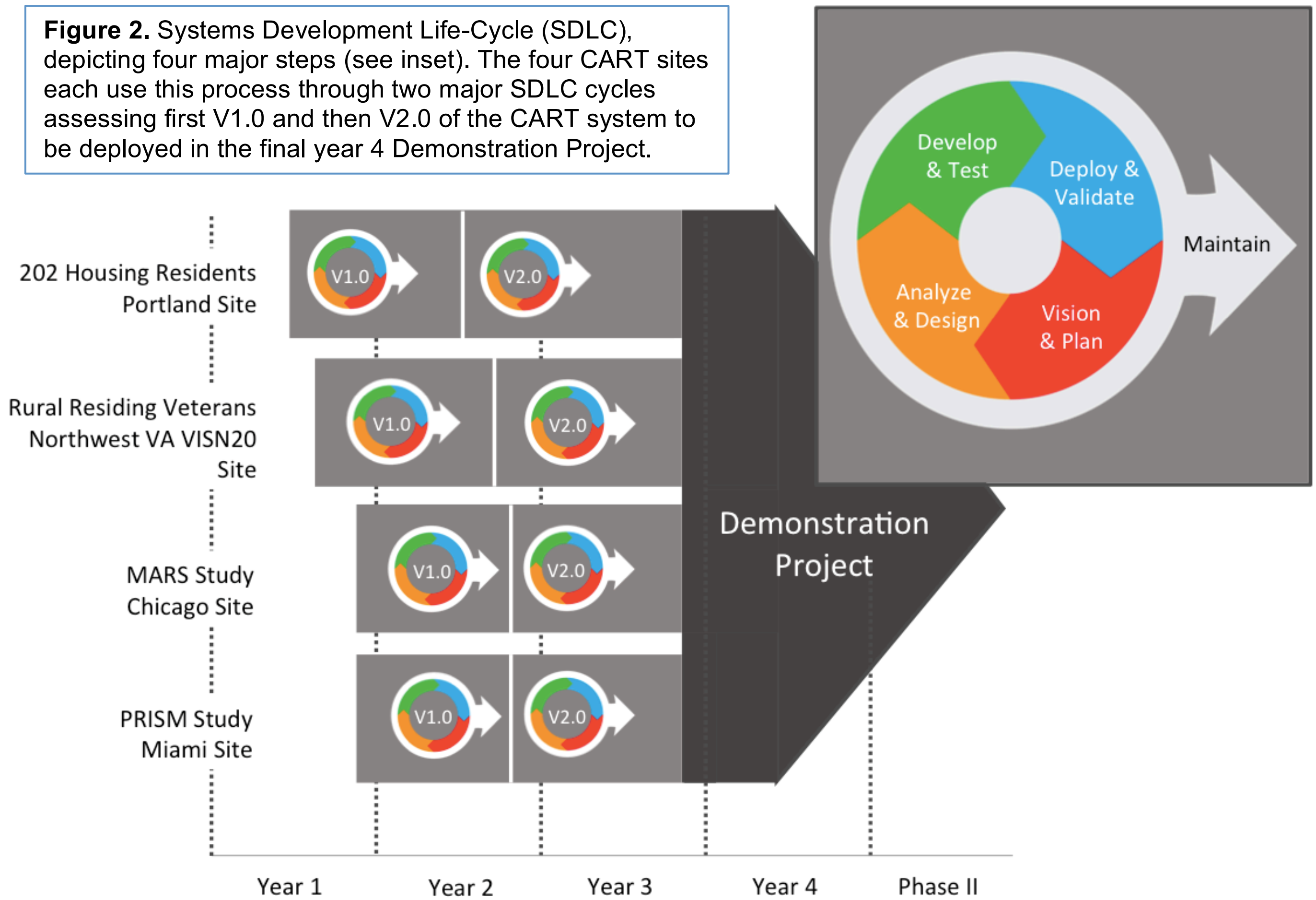
of the research and use of CART shared resources. Investigators using data from the CART database shall provide an overview on the method(s) used to collect the information and acknowledge CART. This is especially important in the case of CART where we want to insure that any algorithms or analysis routines in particular are clearly documented or available to facilitate ongoing research by others. Authors must submit their manuscript to the CART **Information Dissemination and Publications** Committee to ensure the data are referenced appropriately and CART and its sponsors are acknowledged. We would not perform detailed scientific review; we leave this to the peer review system. We will encourage investigators to notify us when a publication is accepted. This information will in turn be forwarded to the CART **Communications Committee** for appropriate further transmission of newsworthy results to the research community and general public.

3.3.4 Documentation. Because scalability and sustainability are core values, documentation will be key so that any group in the future can take advantage of the knowledge and protocols generated by CART. The team will take advantage of building upon already existing infrastructure to "hit the ground running". Thus the SILvR network created a policy and procedures manual (See **Appendix**) that our CART proposal immediately can build upon. Sections identified to be covered for CART (others may be directed by the Steering Committee or Cores): (1) Organization, Roles and Responsibilities (describes the organization of CART and defines the role and responsibilities of each of its parts); (2) Policies (codifies the governing policies of CART; includes handling of intellectual property, publications as noted above). (3) System Development Lifecycle Requirements (codifies the means by which systems and technological solutions will be developed, revised, managed and recorded. This includes an emphasis on the user requirements that CART technologies will enable. As part of this effort, specific systems and components that are initially proposed, as well as integrated iteratively later will be specified here); (4) Deployment Manual (covers details for field deployment including personnel training, sample consents, technical setup instructions); and (5) Data Systems Manual (details system architecture, software specifications; security protocols, rules for access). It is emphasized that this is a 'living' document that will grow over time as lessons are learned and experts are engaged. Thus through this process we will establish and implement the basic processes needed to develop and sustain the technology-based infrastructure of CART. (This includes establishing and coordinating requirements, standards, specifications, and resources for AiP research.)

3.4 Create the scalable demonstration research system. This aim focuses on designing the overall infrastructure and identifying and qualifying equipment and software in line with the expected data models. This work all leads to the Demonstration Project of year 4. Guided by CART leadership, the **Administrative, Resource** and **Data Cores** will work closely together to create the overall CART infrastructure. Proposed project procedures will initially be built upon the current technology agnostic ORCATECH Life Laboratory infrastructure tuned to address the major life domains identified as important for AiP (**Section 3.1**, above). At its center is a platform that has been iteratively developed over the past decade that includes a complete end-to-end system. Importantly, because of the sustained longevity of this system, it forms a natural incubator for iterating on new technologies and opportunities as the original system itself has by necessity been systematically incrementally updated as certain technical capabilities (e.g. low energy Bluetooth beacons, smart watches) have come online. As noted we will also build on resources developed by other members of our team such as those available in CREATE. As further detailed in the **Resource Core** this means that all CART infrastructure and research processes can be up and running quickly, modifying and adjusting rapidly to any new constraints or requirements. Based on extensive interaction with the leadership and advisors of CART within the first nine months the AiP requirements that will drive technical specifications, metrics and outcomes will be established and encoded. In parallel, additional data system infrastructure, both software and hardware will be brought on-line and documented. The current data infrastructure we will build upon has been designed to facilitate scaling by bringing on virtual machine modules (Apache Spark units) that allow the expansion of system requirements (storage and processing capacity) to be modularly added at relatively low cost. This is further described in the **Data Core**. The aggressive time-line will be facilitated by the experience of our industry co-investigators who are used to generating deliverables on quarterly deadlines.

3.4.1 Designing an illustrative study protocol for the final demonstration project. Further guided by the Steering Committee and external advisors, and based on the overall principles of encompassing the capacity to assess the major life domains most important for AiP, a first iteration research platform ("V1.0") will be designed to lead ultimately to the illustrative final Demonstration Project to be run in year four (see **3.3.5** below). This first instantiation of the platform built upon the existing ORCATECH system (as noted above), will be deployed sequentially over the ensuing initial 12 months in activity cascades recurring throughout the four-year project at four key test sites (see **Figure 2** and section **3.4.2, below;** also **Timeline in Figure 2 in Overall Research Plan** summary section). A second wave of development leading to a CART V2.0 research platform will be conducted beginning at the end of year two and extend through year three. V2.0 will be the platform to be deployed to test the hypotheses of the Demonstration Project. V1.0 development focuses on human factors/user centered design and basic technology deployment in the diverse communities; V2.0 focuses on development and deployment of novel needed technology capacities. The development sites represent potentially challenging environments and research or patient populations: 1) Octogenarians living in section 202 housing (J. Kaye, PI; OHSU; Low SES oldest old); 2) the Minority Aging Research Study (L. Barnes, PI; Rush; African American elderly); 3) Clinical V-Tel (CVT) Veterans telemedicine program (D. Erten-Lyons, PI; VA VISN 20; rural, isolated veterans); and 4) the PRISM (Personal Reminder Information & Social Management System) aging cohort (S. Czaja; University of Miami; low-income, minority elderly).

Figure 2. Systems Development Life-Cycle (SDLC), depicting four major steps (see inset). The four CART sites each use this process through two major SDLC cycles assessing first V1.0 and then V2.0 of the CART system to be deployed in the final year 4 Demonstration Project.



3.4.2 Developing and refining the infrastructure. CART research infrastructure and process development will be continuously informed by the initial design, study requirements, user-testing and iterative system deployments. At all stages usability and acceptability of hardware and software technology, communications and feedback interface(s) need to be considered for the entire CART ecosystem. As noted above, a standard SDLC process will be employed through all phases (V1.0 and V2.0) including requirements, design, implementation, testing, installation and maintenance. The requirements will follow an industry-standard "shall"/"should"/"may" format. The requirements are further translated into the design phase system architecture and specifications. In addition, we will adhere to user centered design principles. The **Administrative, Resources**, and **Data Cores** must approve all design phase products before implementation and testing of components or systems proceed. To enhance incremental improvement of the overall research system each site will enroll, deploy and assess in first waves of 30 homes (120 total homes for this phase). The Portland based Life Laboratory group with years of experience in developing AiP technology will initiate the cascade of development and deployment in the octogenarians residing in Section 202 housing. This group will be responsible for the training and visits to the other sites. As needed, the Point of Care Laboratory may be used for focused technology testing prior to deployment (see Overall Research Plan, **Figure 1**). The primary focus of V1.0 deployment will be understanding the unique needs of the use cases, understanding the users (e.g. with interval surveys, user testing and focus groups), refining the metrics and problem solving technology integration and remote deployment. The CART leadership will guide these efforts and strive to be responsive to the inevitable introduction of improving technologies.

With the emphasis on scalability and usability a few cardinal development challenges may be anticipated. Based on our experience, a number of workshops and the literature, refining the deployment process and ensuring that the system and its assessment capabilities are most applicable to the widest number of use cases is critical. Thus, as further described in the **Demonstration Project** section, we foresee the need for improvements to V1.0 in several areas. These will be achieved within the development cycle of V2.0 and include: 1) establishing functional activity and co-resident location within a home using a Bluetooth beacon - smart watch system; 2) focusing on assessing out of home activity including objective assessment of driving; and 3) creating “STAR” (Scalability of Technology for Aging Research), a scalability technology assessment tool for predicting feasibility and successful AiP research deployments anticipating the needs of Phase II. Similar to V1.0, V2.0 will be established and deployed passing through our SDLC cycles throughout year 3. Again, this will be done sequentially in a cascading manner, adding another 30 homes per site providing a final total of 60 homes per site with approximately 360 total participants (about half will live alone in this population). Thus, by year four, 240 homes’ participants will be consented and ready for the year four Demonstration Project. In this way based on lessons gained during years 1-3 and input from the CART Steering Committee and Scientific Consulting Panel, appropriate development, deployment and revisions will be carried forward.

3.5 Demonstration Project. The principles of research operation and conduct established and refined in the development phase leading to the Demonstration Project will continue to be practiced throughout the final year. The Executive Committee (which includes the site leaders) will closely monitor each of the four sites with weekly automated on line reports on the status of each site (further described in the **Resource Core**). This includes review of CART project dashboards developed and refined during the prior development years accounting for such metrics as ongoing enrollment status, technology functionality and data integrity. These reports will also be available to the Steering Committee. Emphasis will be placed on sustaining preset project goals with timely data analysis, presentation and publication of results. This will be critical for proactively planning Phase II before the end of the Demonstration Project. In this light, we have chosen to enroll our four individual CART cohorts from the development phase into the larger hypothesis testing study of year 4 rather than enroll an entirely new cohort because: (1) this provides the opportunity to assess the user experience (of both older residents *and* research teams) across several years and changes in technology and protocols; (2) there is exceptional value to the overall longitudinal big data (which in some cases for many of the basic system metrics will span up to three years by project completion) and its relation to the additional number of independence-threatening life events (e.g., falls, illness, loss of social support) that will be captured with this approach for planning Phase II; and (3) this design affords a potential immediate pathway for directly scaling to many additional sites by adding large, on-going longitudinal studies focusing on aging and older adults.

3.6 Challenges and Sustainability

There are several potential challenges to the overall research proposed. First, technology itself may of course fail or falter during development. We mitigate this potential concern by having a system that is particularly flexible and agnostic. We are not obligated to a particular device, system, or company. The system design allows an alternative sensor, device or software environment to be readily substituted or incorporated. Further, the involvement of our industry colleagues and their wide reach to state of the art alternative technologies or solutions further mitigates this concern. For example, in piloting a wearable system for this proposal, Intel allowed us to rapidly connect to specific companies and experts to scope the available hardware and API’s needed and make a rapid, informed go-no-go decision about this development. A second potential challenge resides in the nature of conducting field studies with older adults. Often the Achilles heal of many projects is enrollment. Although we have made particular effort to ensure that the project leaders are highly experienced in this kind of research and the cohorts to be engaged are of sufficient size to ensure success, we recognize that one should never underestimate this aspect of research. This is especially true given the nature of the cohorts we intend to enroll. We will closely monitor enrollment and retention of our cohorts. In each case there are hundreds of additional subjects available at each site beyond the focus groups we initially will engage (> 500 additional 202 housing residents; thousands of veterans in VISN20 with dementia or Parkinson’s disease, over 500 members of the MARS cohort, and over 200 additional PRISM participants available in the greater Miami area.) Third, over the life of a project, research team members may transition to other projects or institutions. By design our organization has created co-leaders that creates built-in coverage for possible major personnel transitions.

Finally, we must consider sustainability. No doubt, this is not just a question of technical capacity or expertise, but ultimately a question of how to generate adequate resources to sustain the infrastructure and the personnel to maintain the enterprise. Several key basic functions are required ranging from continuous monitoring of the system's backbone or technology infrastructure to the curation and maintenance of the accruing diverse data. Many of these tasks are very simple, but easily overlooked. For example, although there is universal preference to use wireless sensors or devices, in many cases this may mean that in a deployment of just a few hundred homes, thousands of sensors in these homes within several years may need their batteries replaced. In this case a technical team, must be ready to respond. Similarly, one may desire to have a widely used, open-for-research database. However, the database will need to be maintained by persons knowledgeable about these kinds of data. Inevitably data use questions arise from interested new investigators. Despite the best of annotations and on-line data dictionaries, to be most useful, it is highly desirable to have dedicated personnel to answer these queries. Considering these needs, there are several models for achieving the goal of sustaining the CART infrastructure. The SILvR Network Initiative originally worked with industry, NIH, NSF and the Robert Wood Johnson Foundation to start a national research infrastructure similar to CART. The funding goal was to engage industry and foundations through the Foundation for NIH to provide the millions of dollars necessary to scale up this vision. Unfortunately, at the time, there was not enough momentum or dollars at the industry level or among federal agencies to sustain this model. This may in part have been a result of timing (the recession; the early years of the Big Data and Internet of Things movements). Thus, we suggest that this may still be a valid model worth pursuing as CART rolls out its infrastructure.

Among sources of support for this effort that have considerable interest in technology and its potential beyond federal agencies (NIH, NSF, CMS, VA) are the nursing, assisted-living and home care industry and the pharmaceutical (Pharma) and medical device industries. The nursing and assisted-living industries unfortunately, from a financial standpoint are challenging in that much of the residential care business even with technology relies on many components, ranging from training staff to satisfying regulations. The AiP market of older adults currently living independently may be a related sector with more promise in that the growing market of baby boomers are increasingly more technology literate. Some companies are beginning to transform the outlook for this home-focused segment. In the words of David Inns, CEO of GreatCall: "What's really needed by most of the industries being targeted are *scaled, reliable solutions*. We're talking about people's lives at stake, based on the quality and reliability of the service being provided. A Silicon Valley startup that just decides to start serving seniors hasn't necessarily put thought into the details and the fact that lives are at stake. Fall detection can't just be some engineers in a back room who played around with an accelerometer and put it in a device and called it fall detection [20]". Providing evidence of efficacy and scalability of technology-assisted solutions will improve this outlook. An important additional supporting sector to consider is Pharma. There is a growing interest in this sector for digital health integration at many levels [21]. In particular, the potential for improving the conduct of clinical trials (improving outcome measurement, reducing sample sizes, length of trials and costs) through pervasive computing solutions is promising [22, 23].   Thus investment in interventions using CART technologies is quite attractive especially for treatment of chronic diseases that clearly bear on maintaining independence. Precedent for considerable investment by Pharma through FNIH for perceived value to industry is found in the Alzheimer's Disease Neuroimaging Initiative (ADNI) established over a decade ago with significant investment by Pharma. The Critical Path Institute has agreed to facilitate CART efforts in this direction working with Pharma and the FDA as this research moves forward (see support letter).

An additional pathway synergistic to private investment would be to create a neutral not-for-profit CART entity that could own the IP that will be developed conducting CART research. Revenue generated through licensing of this IP would then go toward sustaining the CART infrastructure. A new hybrid may well be the best approach where established aging studies using grant support, integrate CART technology to improve their data capture or intervention strategies, while industry augments these efforts to obtain data of value to their enterprise and other interested parties invest in licensed use of the tools and products generated by CART over time. We propose to pursue these avenues among others during the conduct of our CART research program. Our CART leadership including the **External Relations Committee** will be instrumental in these efforts. We will work closely with the Steering Committee, industry and other key stakeholders to explore these kinds of supporting mechanisms to provide durable support for the research enterprise being created.

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Budget Justification: Administrative Core

ADMINISTRATIVE CORE A: PERSONNEL

Principal Investigators

This proposal uses the Multiple-PI Leadership mechanism. Because the project involves both significant technical work and significant clinical work, the multiple-PI mechanism allows the individuals with the best expertise to oversee each area of research. Moreover, as outlined in the Leadership Plan, The PD/PI's have been working together as a team on related research for more than ten years and have an established and effective working relationship.

Jeffrey Kaye, MD *Co-Principal Investigator and Contact PI, Administrative Core Co-Lead (3 calendar months in years 1-3, 4.2 calendar months in year 4)*
Dr. Kaye is Professor of Neurology and Biomedical Engineering at OHSU and Staff Neurologist at the VA Portland Health Care System. Dr. Kaye has spent over 25 years in human aging research as PI of a number of multidisciplinary longitudinal aging studies funded by the VA (the Oregon Brain Aging Study, now in its 24^{th} year), as well as NIH (e.g., Bioengineering Research Partnership, Intelligent Systems for Assessing Aging Change ISAAC cohort, AG024059; Ambient Independence Measures for Guiding Care Transitions, AIMS cohort, AG042191) and other agencies. This research has focused on why some people remain healthy and functional into very advanced ("oldest old") age while others lose their health and independence at earlier times. Dr. Kaye is also the Director of the NIA - Layton Aging & Alzheimer's Disease Center (LAADC) and the NIA - Oregon Center for Aging & Technology (ORCATECH), an NIA Roybal Center (P30AG024978). Dr. Kaye is internationally recognized for his work on healthy brain aging and most recently, for his translational research leading to the ORCATECH pervasive computing technology model for conducting clinical studies. Dr. Kaye also serves as past Chair of the national Alzheimer's Association's Working Group on Technology and is a Commissioner for the national Center for Aging Services and Technology (CAST), positions which provide ready access to national authorities for relevant advice and counsel.

Dr. Kaye's commitment as principal investigator is based on extensive experience as director of major collaborative research projects and centers. Dr. Kaye, will serve as contact PI and assumes fiscal and basic administrative management including maintaining communication between PD/PI's and all the Core leaders, Site-PI's and other key personnel through regularly scheduled meetings as outlined in the Administrative Core. He will be responsible for communication with NIH and submission of annual reports. Dr. Kaye will also be responsible for the oversight of all clinical aspects of the program, in particular supervision of the four cohort sites for system development and the Demonstration Project.

Stephen Agritelley, *Co-Principal Investigator (1.2 calendar months per year; in-kind)*
Mr. Agritelley is Director of Innovation and Pathfinding, Health and Life Sciences at Intel Corporation. He has broad experience defining experience-driven health and life science solutions that fuel Intel's innovation pipeline and long term growth. He leads global teams that conduct business, technology and usage research, incubating new health and life sciences solutions, as well as providing go-to-market strategies in specific health market segments. Mr. Agritelley's work was an integral part of the product strategy for Care Innovations™, an Intel-GE Companoy, a joint venture between Intel and GE. He was also responsible for driving an international presence in personal health research in the Behavioral Assessment and Intervention Commons (BAIC) effort including the Technology Research for Independent Living Center (TRIL) in Ireland, a 30 million dollar co-investment with the Irish government, as well as working closely with Dr. Kaye and his team in creating the "Living Laboratory" in the Portland Metro area in collaboration with the Oregon Center for Aging Technology (ORCATECH). Mr. Agritelley is particularly skilled in bridging the gap between academia and industry, and in managing and building relationships across multiple disciplines and work cultures to achieve far-reaching goals.

As Co-Principal Investigator, Mr. Agritelley will be responsible for management and oversight of the technical teams; oversight of the design, development, testing and deployment of any needed hardware or software modifications or updates; maintenance of the technical data; and refinement and maintenance of the assessment platform in participant homes. He will also be responsible for providing lead consultation to external engineering or technically oriented researchers and companies needed in development as the CART project evolves. He will work closely with Dr. Kaye to provide input into the ongoing requirements of the CART system and the development of the sharing and dissemination plans.

Further details of both PD/PI's responsibilities is found in the CART multiple PD/PI leadership plan section.

Co-Investigators

Judith Kornfeld, MBA *Co-Investigator, Administrative Core Co-Lead, and Chief External Engagement Officer (1.8 calendar months in Years 1 and 2; 2.4 calendar months in Years 3 and 4)*
Ms. Kornfeld has served as Chief Operations and Business Officer for ORCATECH for the past three years, responsible for identifying and developing potential university-industry collaborations and navigating IP issues. Prior to joining ORCATECH and OHSU she held international positions as Vice President for Business Development in Pharma and the medical device industry (TransPharma Medical, Notal Vision, Impulse Dynamics). She is particularly accomplished at identifying in-and-out licensing opportunities in industry and academic institutions, negotiating agreements, raising financial capital, obtaining grant funding, and building strategic alliances. Her experience will ensure our CART program will be able to rapidly and effectively engage the private sector for appropriate vital input. Ms. Kornfeld will work with the Steering Committee to further develop novel policies and procedures to take advantage of these relationships. Ms. Kornfeld will serve as co-leader with Dr. Kaye of the Administrative Core and as Chair of the External Relations Committee, which will oversee developing standard CART memorandums of understanding, confidential disclosure agreements, conflicts of interest declarations, material transfer agreements and other critical relational policies and procedures. She will work closely with the Ethics and Policy Committee.

Jason Karlawish, PhD *Co-Investigator (Subaward to University of Pennsylvania; 0.6 calendar months in year 1; 0.36 in years 2-5)*
Dr. Karlawish is an Associate Professor of Neurology at University of Pennsylvania and will chair the CART Ethics and Policy Committee, which will facilitate development of guidelines and procedures related to CART governance in the pre-competitive space. Areas will include human subjects (with attention to issues of privacy, confidentiality, and consent); data and data systems; disclosure of intellectual property, corporate and private relationships (with attention to identifying and managing relationships that present conflicts of interest); development of a "user-centered design approach" that ensures the needs, abilities and preferences of diverse user groups (older adults with and without various diseases, providers, caregivers) are accounted for in system design, and includes these users in usability testing of these products; and publications. He will develop a system for declaring conflicts of interest and ensuring that transparency of interactions is maintained throughout the project.

Katherine Wild, PhD *Co-Investigator (0.24 calendar months in Years 1-5)*
Dr. Wild is an Associate Professor of Neurology at OHSU and a psychologist who specializes in the assessment of Mild Cognitive Impairment and technology use by the aging including computerized cognitive assessment methodology. She is an active ORCATECH researcher and has conducted numerous focus groups and technology assessments with older adults and baby boomers to determine optimum communication channels for sharing technology-derived information with lay individuals and health care professionals. As Co-Investigator on the Ambient Independent Measures for Guiding Care Transitions (R01 AG042191), Dr. Wild has led the scientific efforts of the project to identify useful AIMs metrics for care transition professionals, including forming partnerships with appropriate stakeholders. Dr. Wild will participate in the Ethics and Policy Development Committee as well as provide expertise to the Resource Core with regard to user-centered design and assessing attitudes and beliefs about technology.

Lisa Barnes, PhD *Co-Investigator (Subaward to Rush University; 0.12 calendar months in years 1-5)*
Dr. Barnes is Professor of Neurology at Rush University. In addition to being site PI of the Minroity Aging Study Cohort for CART (see below), within the Administration Core scope of committee activity she will participate in the Ethics and Policy Committee. She will bring an important perspective to this group with regard to particular expertise working with underserved populations in research.

Additional Participation on Ethics and Policy Development Committee: Dr. Deniz Erten-Lyons (site PI for Portland VA site of Demonstration Project) and Dr. Sara Czaja (site PI for Miami site of Demonstration Project) will also actively participate with the Ethics and Policy Development Committee. Their participation is included in their effort as site PIs.

ADMINISTRATIVE CORE B: OTHER PERSONNEL

Tracy Zitzelberger, MPH *Administrative Director, Senior Research Associate (3 calendar months Years 1-5)*
Ms. Zitzelberger is an experienced grant manager and has worked with ORCATECH since its inception as the ORCATECH Roybal Center for Translational Research on Aging (P30 AG024978) in 2006. She is also grant administrator for the Oregon Aging & Alzheimer's Disease Center (P30 AG008017), and is familiar with complex grant mechanisms. She will serve as the CART administrative manager, handling all fiscal matters and contracts to ensure compliance with applicable regulations and agency reporting requirements, as well as ensuring research activites are properly documented. She will be responsible for planning Steering Committee Meetings in the D.C. area. Having worked over 15 years in Dr. Kaye's research group, she has experience in all aspects of Dr. Kaye's research lab and serves as a unifying force.

TBD *Communications Coordinator, Research Assistant (1.2 calendar months in Years 1 and 2; 4.2 calendar months in Years 4-5)*
This position will serve as webmaster and communications specialist, responsible for developing and maintaining CART's online presence including social media, as well as coordinating activities of the External Relations Committee. He or she will work closely with CART committees to ensure effective online communication of project activities, including presentations, conference participation and professional publications. We have requested more effort in the latter two years of the grant to accommodate increased CART activity generated.

ADMINISTRATIVE CORE C: EQUIPMENT: None

ADMINISTRATIVE CORE D: TRAVEL

D.1. Steering Committee Travel: As required in the FOA, we request funds to support CART's key personnel (including Dr. Kaye, Ms. Kornfeld, Ms. Zitzelberger, Drs. Dodge, Chiang, Czaja and Barnes) to travel to Bethesda for twice-yearly, in-person meetings. We request $2,000 per person for each trip (airfare, lodging, per diem reimbursement) for six people twice yearly - $24,000 in years 1-3. We request additional funds for this travel in year 4 to support critical members of the CART staff to attend - $50,000 in year 4.

D.2. ORCATECH-Hosted Travel: We request funds to support travel by CART's key personnel and demonstration project staff to meet in Portland, OR for orientation to and training on the CART platform. We request $2,000 (airfare, lodging, per diem reimbursement) for seven people in Year 1 only.

D.3. ORCATECH Training Travel: We request funds to support travel by CART personnel based in Portland and ORCATECH to demonstration project sites at Rush University and University Miami for hands-on training in the field. We request $2,000 (airfare, lodging, per diem reimbursement) for four people in each of Years 1 and 2.

D.4. Conference Travel: We request funds to support travel by CART investigators to attend and/or present at professional conferences. We request $3,500 in Year 1; $4,000 in Years 2 and 3; $8,000 in Year 4.

ADMINISTRATIVE CORE E: PARTICIPANT /TRAINEE SUPPORT COSTS: None

ADMINISTRATIVE CORE F: OTHER DIRECT COSTS

F.1. Materials and Supplies: Teleconferencing Services. We request $500 each budget period to cover subscription to GoToMeeting.com; this web-conferencing service will be vital to facilitate communication between CART investigators and collaborators, as well as the CART Steering Committee.

F.2. Publication Costs: Publication costs are requested in the Administrative Core to support all cores in disseminating findings. We request $2,000 in Year 2; $4,000 in Years 3 and 4.

F.3. Consultant Services: We request support for consulting services to engage the expert counsel of an attorney specializing in Intellectual Property and Patent Law. As required in the FOA, the awardee will be responsible for relevant intellectual property oversight, including establishing appropriate agreements between/among stakeholders for the appropriate sharing of data and appropriate protection of intellectual property. ORCATECH has an established working relationship with Alexander C. Johnson, Jr. In addition to the expertise above, Mr. Johnson is an engineer, as well as an attorney, with decades of legal experience in electronics and computer technology (see Letter of Support). Mr. Johnson will work closely with the External Relations Committee, the Ethics and Policy Committee and the Steering Committee in this groundbreaking work.

Mr. Johnson estimates that, depending on the complexity of the patent involved, creation of one patent in our field costs approximately $25,000, representing about 40 hours at $575 (see Letter of Support). In addition, each patent requires about $5,000 in filing fees. We request funds in Years 3 and 4 to support two patents ($50,000 in attorney's fees, $10,000 in filing fees). This is critical to the sustainability plan.

F.4. ADP/Computer Services: None (see Data Core)

F.5. Subawards/Consortium/Contractual Costs: Subcontracts for Co-Investigator effort will be made with Oregon State University and University of Pennsylvania. Subcontracts for CART demonstration sites will be made with Rush University and University of Miami. A funding request for the VA demonstration site at the Portland VA will be submitted directly to the VA post-award, as described in the FOA.

F.6. Conference Registration: We request conference registration support attendance of CART's key personnel to attend and/or present at national professional conferences. We request $1,750 in Year 1; $2,000 in Year 2; $4,000 in Years 3 and 4.

F.7. In-Kind Contributions: Intel is contributing time for Mr. Agritelley.

Summary: Resource Core

The **Resource Core** focuses on the technology infrastructure beginning with choice of data-driven technologies and technology applications and extending to supporting those systems at multiple points of development, evaluation and sustainability. The **Resource Core** will dynamically craft, implement and maintain the blueprints and procedures guiding the system and technologies to be deployed in the **Demonstration Project**, and the capacity to address standards and upgrades; support diverse evaluation and test protocols and data throughput, user training and outreach, strategic planning; and work with the other Cores and components of CART in the development of public-private partnerships and other models of sustainability. **Accordingly, our aims are to *collaboratively*:**

1. **Establish a technology-based AiP system** that intensively measures multiple domains of function in valid and reliable formats for diverse end user groups and accommodates additional new technologies as the system moves from the **Demonstration Project** to CART Phase II. Included in this aim is integrating the software and data systems processes with the **Data Core** including server and software maintenance and upgrades as well as security and backup processes.

2. **Institute processes enabling the quarterly review of the development, implementation and coordination of the CART infrastructure**. Included in this aim is setting the requirements, standards, specifications, and resources; and identifying and qualifying equipment, software and procedures (incorporating ethics and regulatory policy frameworks) necessary to implement the **Demonstration Project**. This Aim requires in depth coordination and collaboration with the **Administrative** and **Data Cores**, as well as the expertise of the scientific, participant and policy communities.

3. **Establish the infrastructure for resident-centered data capture, retrieval and feedback** enabling installation and monitoring of the technology for CART homes including interactive communications systems, relevant data-based risk stratification processes, help desk and related response capabilities and actions for indicated alerts.

4. **Develop and maintain the data portal for user-friendly access to data (raw and processed), metadata, and visualization tools** in collaboration with the **Data Core** and related domain experts.

Specific Aims: Resource Core

Specific Aims:
The **Resource Core** focuses on the technology infrastructure beginning with choice of data-driven technologies and technology applications and extending to supporting those systems at multiple points of development, evaluation and sustainability. Embedded in the operations of this Core is the need to be dynamic, sensitive to ongoing discovery and adaptation since much of CART Phase I is a development project leading to the **Demonstration Project** of year 4; and ultimately pointing to the larger 10,000 home vision of Phase II. In this light, the **Resource Core** must operate and integrate seamlessly with the other Cores and units of CART. In this coordinated effort the **Resource Core** will be guided, as is characteristic of all successful deployments and sustainable products, by a clear vision of the optimal use cases for aging in place (AiP) technologies. The **Resource Core** takes advantage of building on the ORCATECH system already designed for AiP research as well as findings and resources from other NIH funded Centers such as CREATE. We and others (e.g., [1]) have found that long-term adoption and success is maximized by usability, perceived usefulness, unobtrusiveness, and minimized effort on the part of end users who feel secure in the environments created. The system needs to be sensitive to the needs of diverse end user groups, including diverse cultural/ethnic groups. This includes those at highest risk for losing independence (e.g., an isolated nonagenarian living alone with MCI or mobility limitations), as well as those who will share in the system's capacities such as an adult child or healthcare professional who may review a parent's/patient's mobility profile over time, or a data scientist analyzing high dimensional CART data to develop novel prediction algorithms. The ultimate use case is the testing of future AiP research hypotheses. From our perspective, as further described in the **Demonstration Project** section, the central question for the project is ***determining whether the designed system supports the ability to detect meaningful indicators of independent function in diverse populations and settings***. With this in mind, the **Resource Core** will dynamically craft, implement and maintain the blueprints and procedures guiding the system and technologies to be deployed, and the capacity to address standards and upgrades; support diverse evaluation and test protocols and data throughput, user training and outreach, strategic planning; and work with the other Cores and components of CART in the development of public-private partnerships and other models of sustainability.

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Research Strategy: Resource Core

1. Significance

The Resource Core is charged with establishing and maintaining a flexible technology infrastructure for CART. A central tenet of the Core is that identified use cases for the overall system must inform the selection of what ultimately is a wide range of technologies. There are several inter-related levels of CART use scenarios including use of the platform by AiP residents, clinicians and research teams, use of data and other resources by the overall scientific community and ultimately use in the Phase II large scale deployment. The specific goals and aims of the Phase II project may be considered the most important, but being four years away these are likely to appropriately evolve over time as AiP knowledge and technologies rapidly advance. Whether 10,000 homes is the "correct" number needed to build evidence for the most important use cases will be resolved by the evidence that accrues over the ensuing years.

At this point in time we anticipate several major scenarios driving the selection and design of CART technologies. At the core of these decisions is knowledge provided by current surveys of people concerned with how technology may or may not support desired AiP. Reviews of the literature on motivations and cautions about technology adoption among the older population identify several important themes and gaps [1-3]. In general, most found that if a technology facilitates aging in place (promote independence, safety, less burden on family) and is usable then it would be adopted. On the other hand there were common concerns, e.g., complexity, cognitive effort to learn, cost, privacy, obtrusiveness, forgetting or losing technology. We have found in our research these same common themes with regard to AiP technologies that seniors desire or are wary of [4-6]. For example, consistent concerns have been raised with regard to use of video in the home even if anonymized[3, 4, 7]. Comfort with technology use clearly depends on experience and cognitive ability [5, 8].

Much of the aforementioned research was in the pre-implementation phase; post-implementation perceptions maybe different. In one of the few studies to examine pre- verses post-implementation attitudes, we found among 119 seniors surveyed that there were significant changes in perception once technology was used in homes for a year [6]. Further, these attitudes were different if the person had MCI. Importantly, the perceived benefit or value is not always the same for a senior compared to their adult children [4]. In a recent CREATE study, Czaja and colleagues [9] also found that older adults who had experience using a software application designed for seniors in their homes for a year reported an increase in positive attitudes towards computers. In another ORCATECH supported study attitudes towards technology were different depending on the cultural background of the older person (in this case Hispanic or Korean seniors [10]). Another key group - clinicians - also needs to be considered in use cases for their specific scenarios. A recent systematic review (as well as an in-depth study by our group, including Intel) [11, 12] of clinician and staff views on the acceptability of incorporating remote monitoring technology (RMT) into primary care found a small heterogeneous number of studies suggesting that for RMTs to be adopted in primary care, researchers and developers must ensure clinical relevance, support adequate infrastructure, streamline data transmission into EHR systems, attend to changing care patterns and professional roles, and clarify response protocols.

These lessons learned will be carried forward, informing at every step the choice, design and operation of the CART infrastructure overseen by the **Resource Core**. Thus among the most important functions of this Core is providing responsive infrastructure and procedures for acting on the directions and priorities put forward by the overall diverse CART leadership as development proceeds. This includes not only the developmental work leading up to the **Demonstration Project**, but the **Demonstration Project** itself and ensuring sustainability leading into Phase II.

2. Innovation

The **Resource Core** enables innovation to flourish beginning with the extensible technology agnostic platform of ORCATECH and then employing best practices for subsequent recursive development. In the current research community much research has been largely restricted to time-limited, small pilots, with few well-documented examples of recursive development. In our CART development we will carefully document this evolutionary process so important for future research by utilizing standard development methods including a systems development life-cycle and modified unified theory of acceptance and use of technology [13, 14] approach grounded in user-centered processes to refine and establish the platform for the **Demonstration Project**. We include innovative development and use of reporting methods through a novel Personal Health and Activity Record (PHAR) that combines the functionality of a personal health record with ecological momentary assessment capacity. The latter approach minimizes recall bias while maximizing real-world validity. At the same time, we innovatively capture additional metadata about how individuals complete these records, which provides novel insight into cognitive and motor functions. A unique multidisciplinary team combining the necessary engineering, computer science and human factors expertise needed to ensure success will conduct these activities.

3. Approach

3.1 *Establish a technology-based AiP system that intensively measures multiple domains of function and accommodates additional new technologies.* As noted in the **Administrative Core** we have organized our AiP platform to address five basic life domains (physical and mental health, mobility, social engagement, safety, everyday activities and leisure), enabling monitoring and measurement, screening and diagnosis, and treatment and intervention. We build upon the existing ORCATECH platform [15-31] first deployed in 2004 and installed in over 400 homes since then. In updated form the platform is currently employed for continuous monitoring in several studies covering over 130 homes. The current system has considerably evolved over the years to accommodate new devices and approaches (e.g., smartphones, smartwatches), functionality (e.g. driving assessment), communication protocols (e.g., iBeacons), and data systems (e.g. Apache Spark). At each step, new functionality has been validated through a process of generating ground truth data (e.g., walking speed using a gait mat [32] or visitors for socialization metrics using a video camera mounted *temporarily* at a home's entrance [33] etc.). A summary view of the current ***overall system*** is shown in **Figure 1.** This system and in particular, the 'back end' computing resources, data handling, repository and dissemination aspects are further described and discussed in the **Data Core** section. Further details on system

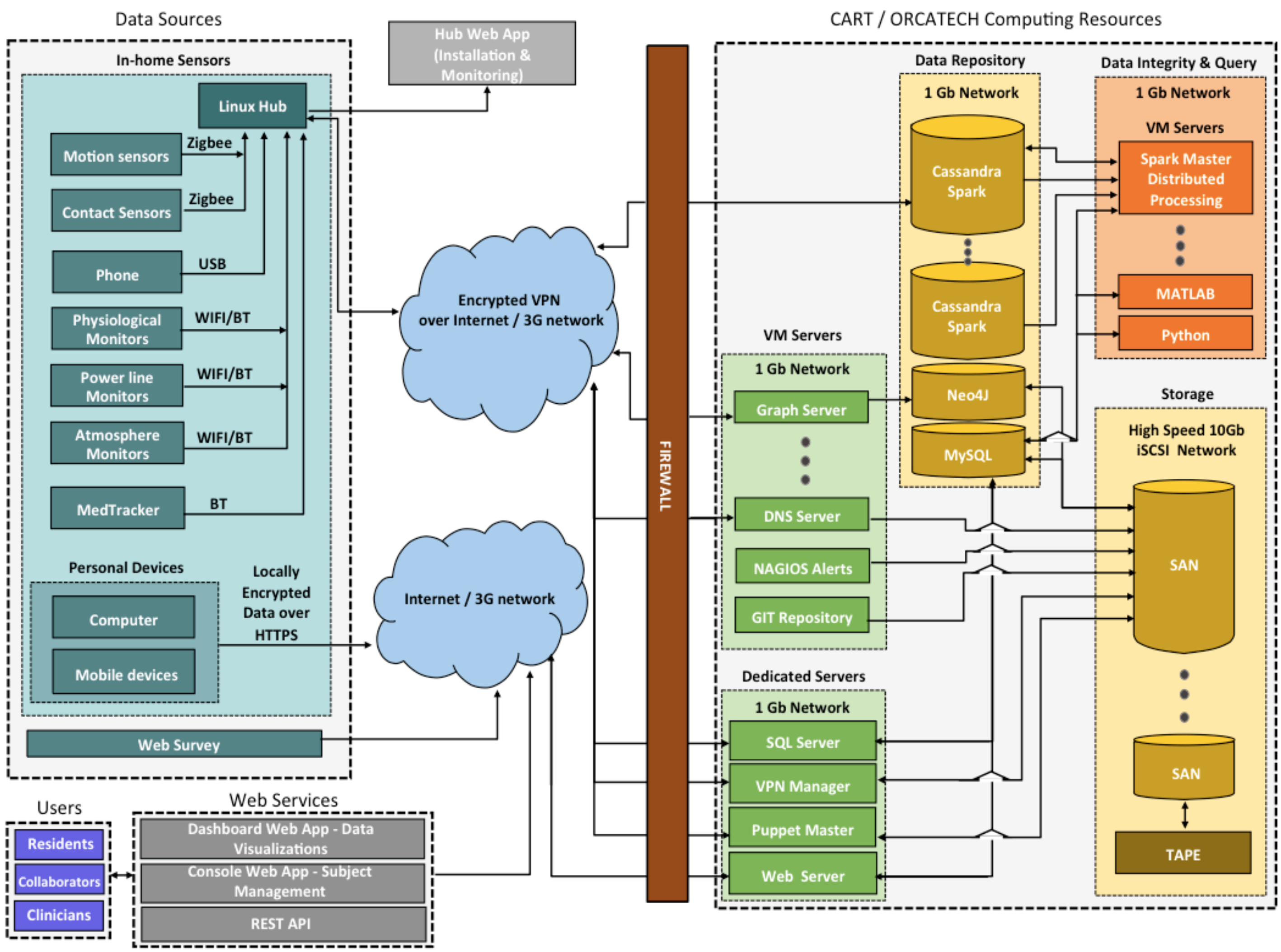

Figure 1. System proposed for CART adopted from ORCATECH depicting the major functional component domains: Users, Web Services, Data Sources and "Back-end" Computing Resources.

functionality,training, installation, deployment, maintenance, validation, and data analysis are found in the **Demonstration Project** section.

Here we describe the 'front-end' of the system, enabling resident-oriented data capture and reporting (see **Figure 2**). **Figure 2** focuses on the functions of the system contained in the box in the upper left corner of **Figure 1** (*In-home Sensors*). *The system is designed to be technology agonistic,* capable of providing the most effective sensing capabilities for specific domains of function. When possible, commercially available devices are used as these provide more direct scalability, often having been produced with attention to existing standards (e.g., electronic, safety, 510K FDA clearance). However, in all cases an API and access to the raw data is a requisite for any technology used. Of note in **Figure 2**, is the box, "Device/Sensor X". This denotes that as long as a new device can provide standard communications connectivity (WiFi, Bluetooth, Zigbee, etc.) it may be introduced into the sensor stream, thus facilitating comparison of new to old devices, as well as helping to 'future-proof' the system as new devices or sensors can thus be rapidly incorporated over time.

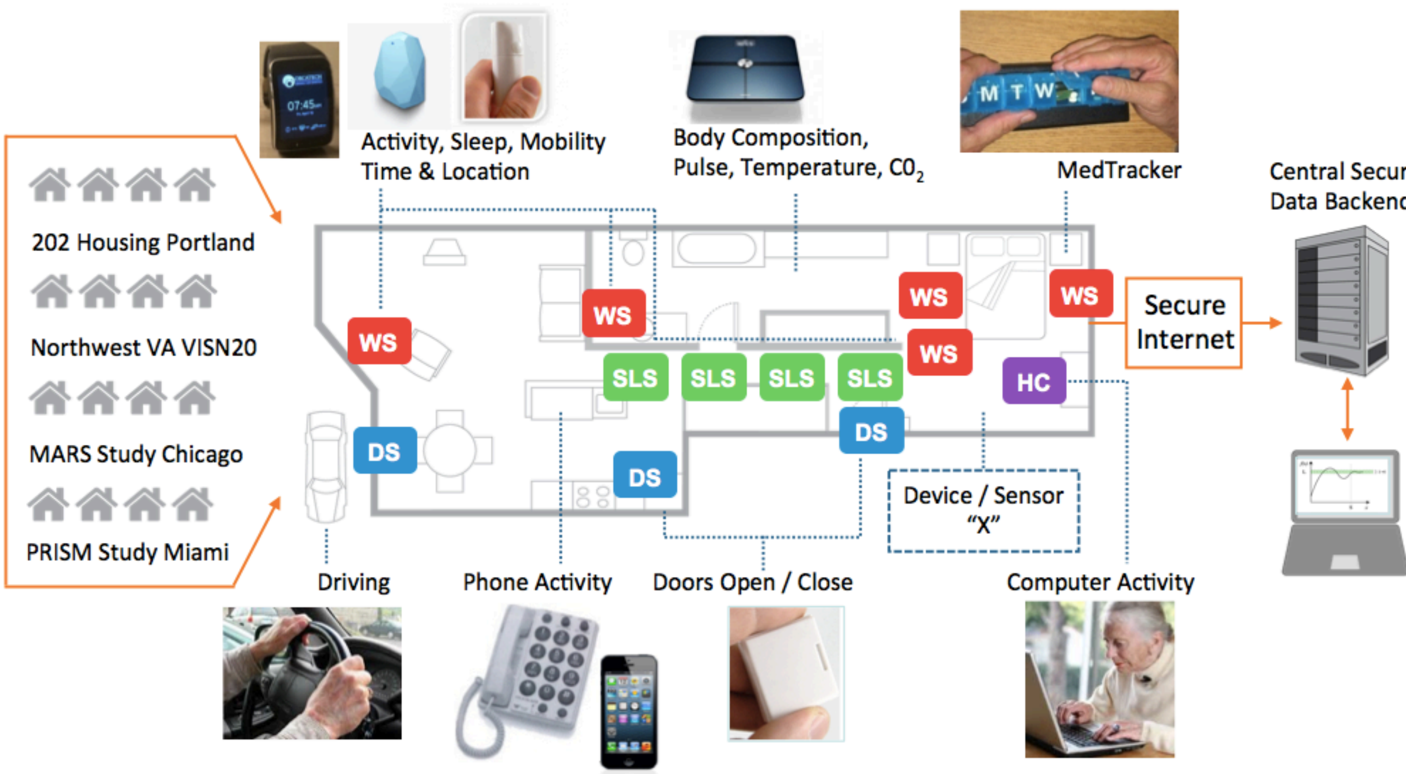

Figure 2. Schematic of home and community based sensing and reporting platform for CART. The Bluetooth Beacon location system and driving activity sensor (installed in driving residents' cars) are part of development in years 2-3 for the **Demonstration Project** in year 4. **Key:** WS = Wall mounted sensor; SLS = sensor line sensor (ceiling mounted); DS = door contact sensor; HC = home computer.

Basic domains are sensed continuously including total daily activity, dwell time by location (bedroom, bathroom, kitchen, etc.), walking speed, nighttime behavior (time of awakening in the morning, time spent in bed at night, wake after sleep onset, times up at night, and sleep latency), medication adherence, trends in physiologic function (BMI, pulse), measures of socialization (outings, phone calls, email sent). These functions (further discussed in the **Data Core** section), are produced from raw sensor data through various levels of aggregation using defined inference algorithms; the same function may be captured by different sensors or devices, but the function can always be tracked backward or forward to ensure research integrity over time.

In addition to the directly sensed data, we have found an invaluable additional data stream must be included, weekly on-line self-report. We call this report a *Personal Health and Activity Record (PHAR).* This brief (on average, 4.2 minutes to complete) weekly questionnaire records activities that are either difficult to objectively sense because they are ultimately internal states (e.g. feelings of pain, low mood, loneliness) or provide specific health and activity data that is best directly recorded frequently from home (e.g. home visitors, ER or hospital encounters, medication changes, injuries, care needs). This is important since most seniors may receive intermittent care at multiple venues (urgent care, nearest hospital, hospital in their plan, private therapist) and one cannot yet rely on a single EHR to provide this data in a timely or accurate fashion for much pertinent AiP information. This weekly interaction via a computer (or tablet) also provides a novel opportunity to sensitively assess cognitive function indirectly or directly as well as fine motor skills [30, 31]. The PHAR is described further below. Given the planned diversity of our samples it is important to note that these systems and questionnaires will be available in both English and Spanish. We will work with our colleagues at the University of Miami site who are well versed in Spanish translation processes, to complete needed translations.

All the data from the sensor network is sent wirelessly to a small "plug" computer dedicated for this purpose. From there the data is sent, depending on use case, either through broadband or cellular connections to our secure server system at OHSU. Sensor data can be sent in real time (e.g. for emergency response applications) or with some delay, typically uploaded nightly (e.g. for trend detection). The data is aggregated into several databases designed to facilitate analysis and quality assurance. The CART data system including data capture and curation, server(s), repository, software, security, maintenance, backup and recovery, updating and paths for analysis and data dissemination is described in the **Data Core**.

3.2 Institute processes enabling developing, building and coordinating the CART infrastructure. This Aim requires careful coordination and collaboration with the **Administrative** and **Data Cores**, as well as the expertise of the scientific, participant and policy communities. As noted in the Significance section above, the foundation for development begins with the end user, e.g., older person. We will use our established current infrastructure to follow an industry standard framework for developing software, a technology system or product, already introduced in the **Administrative Core** section of this proposal (see **Figure 2** in the **Administrative Core**). This is the systems development life cycle (SDLC) cascade [34-36]. This approach allows for integrating at each level the input of all key stakeholders (the end user, the research team, the clinician, etc.). There are multiple variations of SDLC development. We adapt a process suggested for eHealth [37]. System development life cycle for CART will cover 4 main phases per cycle: **Vision and Plan** (set course of action, specifications, overall requirements); **Analysis and Design** (address operational & technical issues, needs assessments, usability tests, lab function studies); **Develop and Test** (develop and integrate system into intended environments, pilot tests); **Deploy and Validate** (implementation, further tests, verification, qualification). Passing through these steps leads to a **Maintenance Phase** which may itself be analyzed further. This process applied to our CART development will transit from our starting platform, through two main cycles leading successively to a CART platform V1.0 and then V2.0 for final introduction into the **Demonstration Project** (DP). This is further described in the DP section. Each cycle will use several key approaches. In particular it will be important to follow standard processes for analyzing user acceptance, such as the Unified Theory of Acceptance and Use of Technology [14] and related models [2, 38]. We will also adhere to the principles of user-centered design and will adopt the well-established protocols developed and used by CREATE [39, 9], which engages representation samples of users throughout the design process.

Although space limits detailed description of the many processes that are to be used to develop the CART system we point out that 'ground truth' validation is particularly important to consider when largely unsupervised sensor data is being captured. Both qualitative and quantitative methods will be employed. For example, rapid prototyping, focus groups or scripted laboratory-based performance of activities (creating learning proxy training sets) or home-based written logs or diaries may be used. These approaches may not capture the true heterogeneity of activities or be burdensome to collect. When possible, ecological momentary assessment (in our case through our on-line connection to the volunteer) is a preferred method, although even with EMA one must be careful as to the specifics and timing of the activity that is being queried [40].

3.3 Establish the infrastructure for resident-centered data capture, retrieval and feedback A key part of infrastructure function will be enabling installation and monitoring of the technology for CART homes including interactive communications systems, relevant data-based risk stratification processes, "call center" or related response capabilities and actions for indicated alerts. Alerts can be related to setting tolerances on the system such as when battery life is waning or related to performance level of an individual research participant such a medication adherence < 80%. These functions will be initiated on the existing ORCATECH platform using the ***Console* software** *(*bottom left, **Figure 1***)* and the PHAR noted above. The Console remote monitoring software provides multiple features with regard to functions needed during development including monitoring the health and status of the system and sensors remotely (e.g., sensor outage), pushing remote software upgrades to homes, and a mechanism for setting and then monitoring quality standards or alerts at the individual or overall study level (see **Figure 3**). These metrics will be set during requirements, specification, and testing phases, e.g., "all sensors and devices will meet functional requirements > 90% of the time monitored in aggregate for each week of study." Tracking these metrics also extends to the specification of quality assurance and provenance checking (tracking data through all transformations, analyses, and interpretations) and data system maintenance necessary to insure ongoing integrity of the overall research.

Figure 3. The Console allows for remote continuous monitoring of the 'health' of deployed technologies and alerting of out-of-range metrics. The figure shows example Console plots (screen-shot) generated on a weekly basis for a current study that shows the functionality of all technologies summarized by sensor or device type for the cohort with number of sensors needing review during the week in red. The inset (on the right) shows the drill-down capacity of the software to assess the function of system components at the individual level and the single sensor or device level (in this case the MedTracker monitoring twice a day drug adherence over three months in an individual as indicted by open pillbox compartment events, plotted as blue points over time). Menu choices are: Custom alerts, date ranges and graphical displays that can be generated on an ad hoc, real-time basis.

3.4 Develop and maintain the data portal for user-friendly access to data (raw and processed), metadata, and visualization tools in collaboration with the **Data Core** and related domain experts. Access to the data is key across multiple stakeholders involved. We have developed several standard visualization and analytic tools for rapid query and display of the data. For example, we have found spiral plots to be of particular value for understanding the relationship of time and activity by location. A spiral plot tool was created to allow the user (in this case focused on the researcher) to be able to rapidly visualize this kind of data at the individual level (See **Figure 4**). We anticipate using this tool extensively for exploratory data analysis. New data analytics and visualizations will be developed as CART development phases evolve. Examples of the potential evolution of this spiral plot function and other analytics are given in the **Data Core** and **Demonstration Project** sections. In addition to facilitating access and visualization of the data for the research team, the ability to generate reports or visualizations of data for end-users (e.g., patients, caregivers, clinicians) is also an important feature that is currently available (See **Figure 5**). In the **Demonstration Project** section we further describe the weekly PHAR that is received in the homes of all current ORCATECH Life Lab participants. As part of CART development we propose to build on this application that is compatible across multiple platforms to specifically understand and improve upon the ability for the diverse older volunteers at the four CART sites to both report health, activity and life events, and to receive meaningful feedback and information.

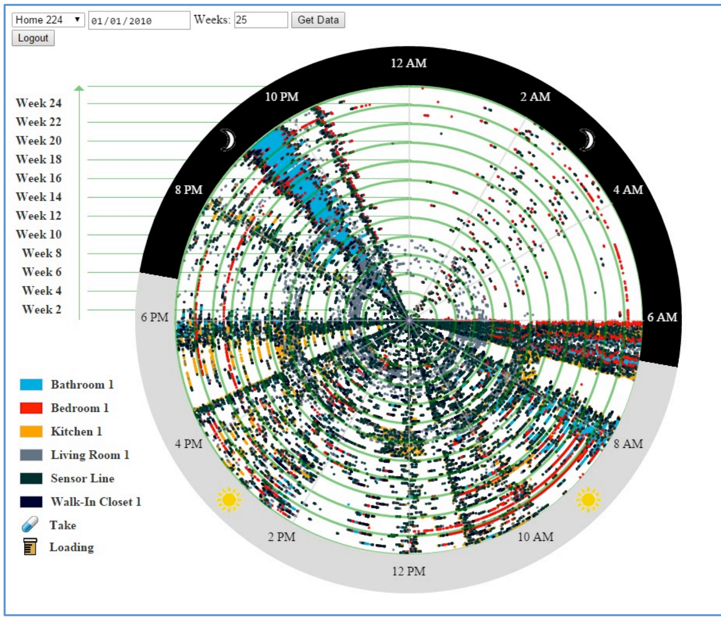

Figure 4. Spiral plot of six months of data for a single home. This is a routinely used data visualization tool that allows flexible windowing of desired date ranges and data types. The data are plotted as a 24-hr clock, with midnight at the top and noon at the bottom. Each day forms one circle. The solid blue circles mark one-month boundaries. Colors indicate which sensor fired: Red = bedroom, blue = bathroom, yellow = kitchen, grey = living room. Note the 3½-week period in which there was a live-in guest who slept in the living room (night-time activity in the living room is apparent; weeks 6-10). Note also the 2-week period when the participant did not leave the apartment for meals, due to a viral epidemic that resulted in a congregation restriction in the community (fourth month). Finally, note the consistent patterns of behavior: bedtime at 2230 hours, up once most nights between 2am and 4am, rise time 0600 hours, a visit from the 'cleaning lady' at 5pm every 2 weeks.

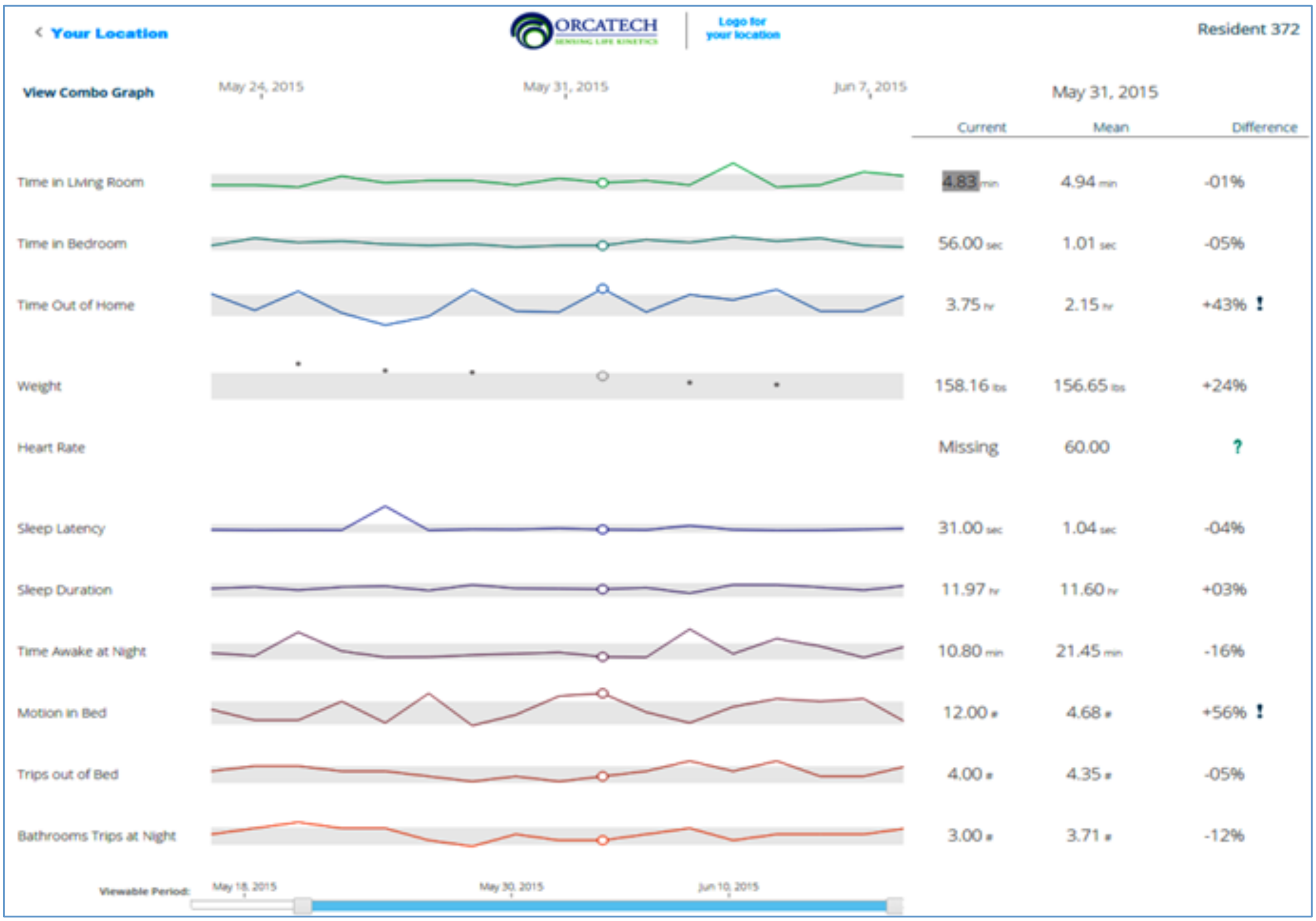

Figure 5. Dashboard display (screenshot) of functions currently being assessed continuously in 100 residents of 7 different retirement communities. The display, here showing data at the individual level, can be customized by the user to show higher-level summaries, single functions, numerical detail, different windows of time (slider function at bottom) and a history of what was viewed and for how long. In this custom view (typically viewed by a clinician or facility staff) multiple functions are displayed (time in home locations, time out of home, physiologic measures, sleep measures, and bathroom trips); the gray shading indicates the pre-set ranges of desired function.

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Budget Justification: Resource Core

RESOURCE CORE A. PERSONNEL

Sara Czaja, PhD *Resource Core Co-Lead (Subaward to University of Miami; 1.2 calendar months per year)*
Dr. Czaja is a Professor in the Departments of Psychiatry & Behavioral Sciences and Industrial Engineering, as well as Scientific Director of the Center on Aging at the University of Miami. Dr. Czaja will be responsible for leading and oversight of the user-centered assessment and evaluation aspects of the V1.0 and V2.0 development cycles as well as the development of the START (Scalability of Technology in Aging Research Tool). She is well recognized as an expert in aging, technology evaluation and behavioral intervention research. Specifically, she has extensive experience in interventions aimed at older adults of varying levels of functional status including MCI patients as well as family caregivers and other patient populations. In addition, she has vast expertise with technology-based interventions, the implementation of these interventions with diverse populations, and usability engineering. A particular focus of her work has been on using technology as a format for intervention delivery. Our approach to interventions is based on a person-centered design, which is commensurate with her background in Industrial Engineering. She directs the NIH-funded, multi-site Center for Research on Aging and Technology Enhancement (CREATE). In its 16th year of funding, CREATE focuses on the interaction of older adults with technology systems in living, work and healthcare settings. She recently completed a cross-site trial, the PRISM trial, which evaluated the efficacy of a software application in enhancing the well-being and social connectively of older adults (aged 65+) who live alone in the community and were at risk for social isolation. Our CART proposal will take advantage of this identified cohort for our research. She is also the Principal Investigator on a project funded by the National Institute of Nursing Research, examining the feasibility and effectiveness of an evidenced-based, culturally tailored, psychosocial caregiver intervention delivered via tablet technology in alleviating caregiver distress.

Patrick Chiang, PhD *Resource Core Co-Lead (Subaward to Oregon State University; 1.8 calendar months per year)*
Dr. Chiang is Associate Professor of Electrical & Computer Engineering at Oregon State University and Adjunct Professor at Fudan University in Shanghai, China. His research focuses on identifying ways to improve the energy efficiency and form factors of electronics with the ultimate goal of applying these concepts to new technologies that can continuously monitor the health of individuals. He has experience in developing solutions for research where there are no adequate commercial versions such as a recently developed wearable solution to monitor 600 subjects in a USDA-funded community based study of nutritional habits and activity. Dr. Chiang will be responsible for leading and oversight of the engineering and technical aspects of the developing CART infrastructure. This will be important for all years of the project, but especially for the development of the multiperson in-home location activity system, as well as the out of home activity monitoring. He will also work with the Data Core to integrate sensor or device generated data seamlessly into the CART data system including reporting systems for multiple users (e.g., the research team, clinicians, outside collaborators). Together, Drs. Czaja and Chiang will work to dynamically design, implement and maintain the blueprints and guiding procedures of technologies to be deployed while addressing standards and upgrades, support diverse evaluation protocols and data throughput, user training and outreach, strategic planning, and work with the other Cores and the components of CART in the development of the overall system.

Hiroko Dodge, PhD *Co-Investigator (0.24 calendar months per year)*
Dr. Dodge is Associate Professor of Neurology at OHSU and director of the Data Core of the NIA - Layton Aging & Alzheimer's Disease Center (which provides the clinical database for ORCATECH studies such as in the current proposal). Dr. Dodge serves as Co-Lead of the CART Data Core, and will work closely with Drs. Czaja and Chiang on Resource Core development and activity. Due to the intertwined nature of the two cores in terms of data and resources being created, effective and timely communication is critical. Dr. Dodge's involvement with both Cores will facilitate their close collaboration. Her expertise includes study of longitudinal trajectories of independent activities of daily living and cognitive functions over time, cross-national comparisons and predictive values of neuropsychological tests, novel cognitive measures, age-associated declines in leisure activities, and clinical trials. She recently completed as PI the first RCT using home-based technologies and monitoring to assess and encourage social engagement in older adults with MCI or at risk for MCI, and as such has an exceptional understanding of the strengths and limitations of the kinds of data to be collected in the CART initiative.

RESOURCE CORE B. OTHER PERSONNEL

Thomas Riley *Technician Research Assistant (7.2 calendar months Year 1; 6 months Years 2-4)*
Mr. Riley's deep expertise in computer science, data systems engineering and most specifically in home-based pervasive computing system set-up and monitoring was already described in the Data Core above. His effort although technically 'split' between the Resource and Data Cores is best considered as a seamless trans-core effort. He architected the current system (Figure 1 in the Resource Core) which contains both the front end capabilities of handling multiple sensors and devices and reliably routing that data from the home to the backend data system which includes the secure data storage, backup and processing functions needed for this project. In the Resource Core as we have constructed the division of labor, Mr. Riley will be more focused on the sensor systems and data capture in the home, the technical support and further needed development of the PHAR, the novel dyad monitoring system using Bluetooth Beacons and smartwatches, and the use of the latter system to monitor out of home activity. He will work closely with Drs. Czaja and Chiang in all these efforts; increased effort is requested in year 1 of the grant to account for ramp-up priorities.

Nicole Sharma *Technical Research Manager, Research Associate (7.2 calendar months per year)*
Ms. Sharma has 10 years of experience managing the ORCATECH Life Laboratory and other large field studies using in-home technology. She has overseen the installation and maintenance of over 500 homes with pervasive computing and sensing systems. She will oversee the field teams for all four cohort sites. She will be responsible for maintaining and updating the documentation and training manuals for setup and deployment of the CART system. She will work with Mr. Davis-Bloom (see below) to create "how-to" videos of the set-up and deployment of the CART system which will be an important product of the CART effort. She will lead staff training for all CART sites, traveling to sites for this training. She will be available on-line or by mobile phone supervising the Help Line (see below) to trouble shoot any problems that arise at the sites in the field. Ms. Sharma will be responsible for IRB and regulatory compliance for the section 202 housing resident cohort, as well as lending her experience in this area to these efforts at other demonstration sites.

Christina Dunn, PhD *Postdoctoral Researcher (3 calendar months in year 1; 6 calendar months years 2 and 3; 9 months in year 4)*
Dr. Dunn is a post-doctoral researcher with ORCATECH. She represents one of two young woman scientists (see Dr. Austin below) who we have engaged in our CART team both because of their exceptional quantitative skills and analytic talent, but also because there is an important need to develop the next generation of scientists to conduct CART research. This is part of sustainability. Dr. Dunn like many 'hybrid' scientists in data science is a physicist by training. She is highly knowledgeable in key programming languages such as MATLAB and Python. She developed the highly specialized algorithms that coordinate the thousands of mirrors needed for the international large-scale telescope being built in Europe. She now wishes to turn her expertise to improving the health of the aging. Thus she will apply her special skills in data visualization, graphical user interface design, hardware and sensor interfaces, and machine learning toward developing improved visualization of the high dimensional data (e.g. see the spiral plot figure in the Resource Core section) and streamlining data throughput by improving the efficiency of the code written to process some of the more data intensive algorithms (e.g. individual mouse movement data tapping computer use, may generate 60 million rows of data for an individual requiring a day to run an analysis program using conventional existing computing power). She will work to refine the out of home activity assessment which combines visualization with quantified activity. In this work she will collaborate with Dr. Austin (see below) who will also be refining algorithms for social engagement and home-based acitivites. Dr. Dunn will importantly also be engaged in assessing the growing array of sensor data ontologies to be integrated with many use cases and work to standardize these into an AiP framework. During the first year of our proposal, she will lead a systematic review of these ontologies in collaboration with our CART team (Data and Resource Cores in particular) and the many important stakeholders that need to be involved in this effort (industry, academic researchers, health care providers, resident end-users) with the express purpose of creating an AiP focused schema for the field.

Johanna Austin, PhD *Postdoctoral Researcher (3 calendar months in year 1; 6 calendar months years 2 and 3; 9 months in year 4)*
Dr. Austin is a post-doctoral graduate of the OHSU Biomedical Engineering program who has developed novel models and sensitive algorithms for assessing social engagement and mood using in-home pervasive computing and sensing platforms. In addition, she has developed algorithms to measure nighttime behaviors

such as scratching ("itching behavior") using actigraphy data. She has expertise in statistical signal processing and machine learning techniques, and in integrating large multidimensional data sets that are typically generated from home monitoring systems such as proposed in CART. Her analytics background and biomedical engineering knowledge coupled with her previous work as a caregiver for the elderly gives her an unusual perspective on the use of technology to help seniors maintain independence in their homes. Dr. Austin will assist with data collection in the Point of Care Lab (for any new or revised technology or devices) and the patients' homes as needed to adequately characterize and understand the data from the sensors in the iterative development phases of the project. She has been instrumental in developing the Bluetooth beacon – smartwatch system for assessing couple's interactions (an extension of her work on social engagement). She will be responsible for assessing this and other technologies as they evolve leading to the Demonstration Project. She will work closely with Drs. Wild, Chiang and Czaja to address the technical aspects of user-needs and modifications., as needed in the collection of requirements data. Dr. Austin will also be responsible for review and cleanup of the sensor data to prepare it for analysis. Working with Drs. Dodge and Crowe (Data Core), Dr. Austin will also be responsible for analysis using current models as well as modifying and developing new predictive models for AiP as described in the Demonstration Project.

Ben Davis-Bloom *Research Assistant (2.4 calendar months in Year 1; 6 calendar months in Year 2; 8.4 calendar months in Years 4 and 5)*
Mr. Davis-Bloom has been a research assistant with ORCATECH for almost two years. He acts as a field technician and has configured, installed and tested all technologies deployed into over 100 senior's homes. For the proposed project, he will monitor the status of all technologies in all homes at all demonstration sites on a daily basis using the Console on-line system described in the Resource and Data Cores (and Demonstration Project) sections; he will identifying any problems, work to fix them remotely and, if necessary, work with demonstration sites to schedule in-person repairs. He will maintain a "Help Line" to provide support to demonstration site staff, as well as participants, to respond to questions or problems with their study computers or CART platform. He will record these interactions in a database allowing retrieval for later analysis where the data may be used to help construct the START for assessment of future scalability. He will work with Ms. Sharma (see above) to create the 'how to' instructional videos to facilitate future deployments.

RESOURCE CORE C. EQUIPMENT: None

RESOURCE CORE D. TRAVEL: None

RESOURCE CORE E. PARTICIPANT /TRAINEE SUPPORT COSTS: None

RESOURCE CORE F. OTHER DIRECT COSTS
F.1. Materials and Supplies

CART Platforms will include the following (or similar): Figure from the Resource Core is reproduced here for reference in terms of the sensors and technologies to be supplied.

A basic platform of sensing technology forms the backbone of the overall system for capturing continuous unobtrusive home-based data. Here we describe elements of the platform (as described in the Resource Core and Demonstration Project; See also **Figure** below.) and include a table detailing specific component costs.

Please note that the equipment requested in the Resource Core will be for three of the four proposed Demonstration Project sites, the Portland 202 Housing, Rush University and Miami University. Equipment to support the Portland VA cohort will be requested as part of the VA budget upon award.

Indoor Activity Monitoring
Plug PC and Ethernet Connection Data Hub: A Plug PC (a monitorless CPU; Dreamplug, Globalscale, Anaheim, CA) and Ethernet connection allow data collection from system devices and transmission back to our secure servers at OHSU without participant interference. The Plug PC is configured to the specific participant and home set-up upon system installation using a laptop and our centralized digital participant management system. Additional data collection devices (such as sensors, phone monitor, MedTracker and scale) are configured by communicating with the Plug PC in this way as well.

IR Motion Sensors and Zigbee USB Dongle: NYCE (NCZ-3041, NCZ-3011, NCZ-3045 NYCE, Vancouver, BC) Sensors are digitally assigned to a given home during system installation, communicating with the Plug PC via a wireless Zigbee USB Dongle (ETRX3USB, Telegesis, Buckinghamshire, UK). One sensor is placed per room at 170 cm (head height) to sense motion within the room and participant transitions from room to room. A straight "Sensor Line" of four sensors at 61 cm intervals is placed on the ceiling of a hallway or other area where the participant walks regularly at a consistent pace. This sensor line allows unobtrusive gathering of walking speed many times per day; thousands of walks a year. Other metrics can be derived from these activity sensors such as dwell time or number of room transitions. Door sensors are placed around the home at all external doors to detect participant coming and going from the home, and on the refrigerator to determine general frequency of food access. Typically, 3 contact door sensors and 15 motion sensors are required per home, along with 3M adhesive to install. In addition to the IR motion sensors, Bluetooth Beacons (Estimote) are also deployed strategically about each home and configured similarly to the IR sensors. Participants will be given a Samsung Gear 2S "smartwatch" custom configured for the project to wear all day. Depending on battery life available at the time of project deployment (this is a rapidly evolving area) each participant may be given two watches, one to wear and one to charge so that the participant is always wearing a charged watch and develops a reliable routine (i.e., always wear the watch). In homes with couples this means that each couple in a household will require four watches (two for each resident).

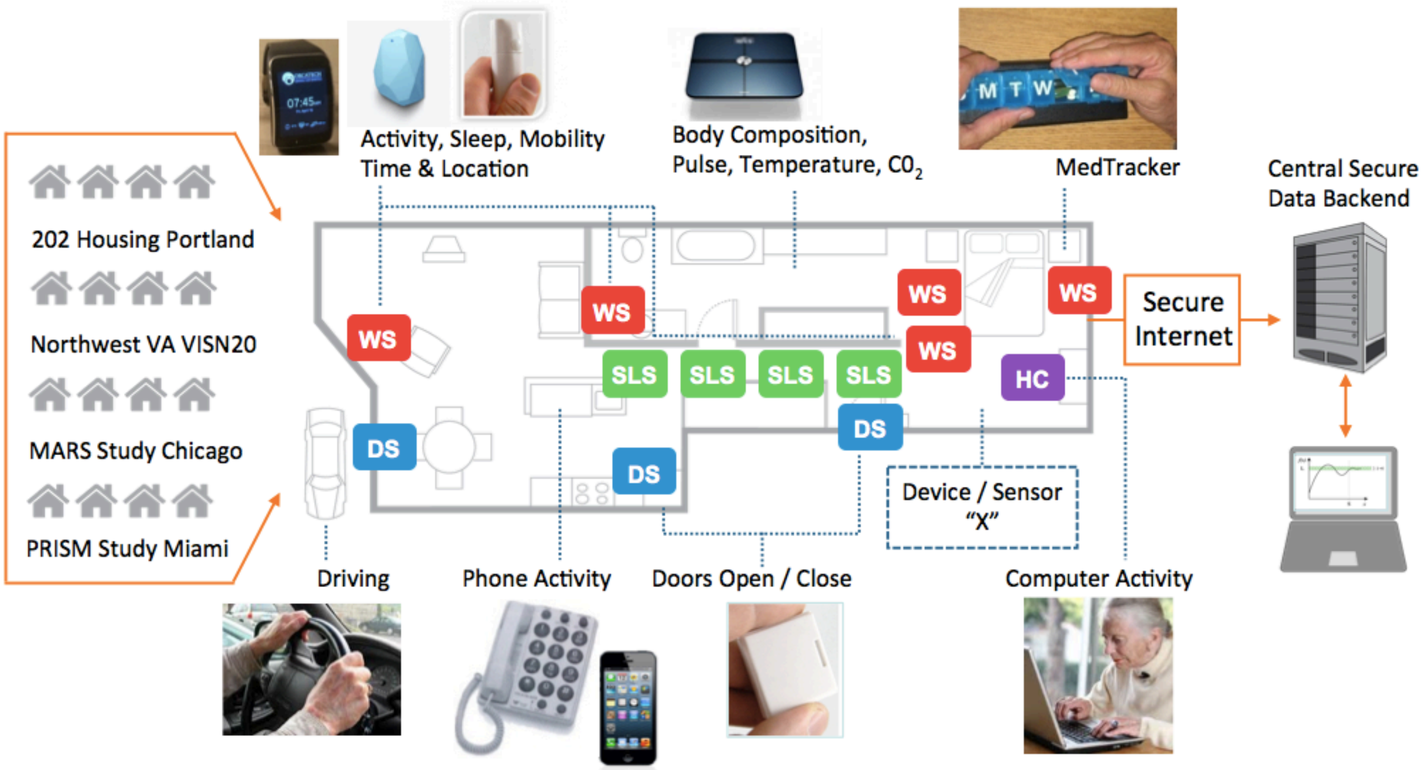

Figure. Schematic of home and community based sensing and reporting platform for CART. The Bluetooth Beacon location system and driving activity sensor (installed in driving residents' cars) are part of development in years 2-3 for the **Demonstration Project** in year 4. **Key:** WS = Wall mounted sensor; SLS = sensor line sensor (ceiling mounted); DS = door contact sensor; HC = home computer.

Outdoor Activity Monitoring: The watch used above will also be GPS enabled and allow for pedestrian tracking outside of the home as described in the Demonstration Project section. In addition, those participants who drive will be invited to consent to having a telematic device (commercial brand: Automatic) installed on the data port of their automobile to facilitate monitoring of driving behavior.

Medication Adherence: MedTracker: As part of the basic platform, an ORCATECH-developed medication tracking device (the "MedTracker") is installed that is a seven day pill box that records whether or not the designated day's compartment was opened and the time(s) that it was opened each day. Participants using the pillbox provide their daily medication regimen to the research staff. This provides valuable information about medication adherence as well as a potential indication of cognitive decline if consistency of medication-taking decreases.

Socialization: Phone Monitor: A phone monitor is placed on landlines in homes with landline phones in order to record call frequency, time of use and whether calls are incoming or outgoing. This device also allows analysis of variation in phone numbers called. If a participant does not have a landline (or has both a landline and a cell phone), cell records are used and entered into a phone database for this analysis. These records provide indicators of social engagement or isolation.

Table: Platform Costs

PLATFORM 1.0			
Item	**#/home**	**$/unit**	**Total**
Hub			
DreamPlug	1	$179.99	$179.99
In Home Activity Monitoring			
NYCE Door	3	$40.00	$120.00
NYCE Motion	15	$50.00	$750.00
3M sticky	5	$4.39	$21.95
Telegesis Dongles	2	$45.00	$90.00
Dongle Plug	4	$3.00	$12.00
CR2 Batteries	36	$1.25	$45.00
Samsung Gear S	4	$329.00	$1,316.00
Beacons	15	$35.00	$525.00
Medication Adherence			
Medtracker	1	$500.00	$500.00
9V Batteries	4	$0.91	$3.64
Socialization			
Phone Monitor	1	$100.00	$100.00
Physiologic Monitors			
Scale	1	$149.95	$149.95
AAA Batteries	20	$0.39	$7.72
		Subtotal 1.0 Platform Per Home	$3,821.25
		Replacement %	10%
		Total 1.0 Platform Per Home	**$4,203.38**
		N Homes; 3 sites	180
		Total 1.0 Platform All Homes	**$756,608**

PLATFORM 2.0 UPGRADE			
Item	**#/home**	**$/unit**	**Total**
Upgrade			
Upgrade TBD	1	$650.00	$650.00
Automatic Car Tracker (58% homes with driver)	1	$50.00	$50.00
		Subtotal 2.0 Upgrade Per Home	$700
		Replacement %	10%
		Total 2.0 Upgrade Per Home Total	**$770.00**
		N Homes; 3 sites	180
		Total 2.0 Upgrade All Homes	**$138,600**

TOTAL PLATFORM COSTS	
N Homes; 3 sites	**180**
TOTAL PLATFORM COSTS	**$895,208**

Physiological Monitoring: A wireless digital bioimpedence scale that collects in addition to BMI, pulse, environmental temperature and ambient CO_2 level (WS-50 Smart Body Analyzer, Withings, Cambridge, MA) is installed in the bathroom to collect data on participants BMI and other indicators. Participants are instructed to stand on the scale each morning. This data may then be correlated with other reported events (e.g., health status), as well as participant heart rate, room temperature, ambient CO_2 level, and other passive indicators of behavior, such as protocol adherence and frequency of use over time.

TBD 2.0 Upgrade Components: We anticipate that there will be new or additional capabilities that are desired to include in this project within the next 2-3 years. This may be new functionality to existing devices or novel and more effective ways of collecting similar or new data. Thus we have budgeted for this likely scenario as part of our overall equipment needs. These are included in Platform 2.0 costs below, as well as $40,000 in year 3.

F.2. Publication Costs: None

F.3. Consultant Services: None

F.4. ADP/Computer Services: None

F.5. Subawards/Consortium/Contractual Costs:

- Subaward to University of Miami for Dr. Czaja's time
- Subaward to Oregon State University for Dr. Chiang's time

F6. Shipping Costs: The CART Resource Core will procure hardware and software necessary to configure platforms for the demonstration sites. We request shipping costs of $60/platform to CART sites in Chicago and Miami based on the anticipated enrollment – $1,200 in Year 1; $7.200 in Year 2; $3,600 in Year 3; $0 in Year 4, as all platforms will be installed.

Summary: Data Core

The **Data Core** is designed to support the access, collection, encoding, decoding, transmission, processing, storage, analysis, display, and distribution of data informing Aging in Place (AiP) research and facilitating subsequent interventions based on those data. The **Data Core** works closely in concert with the **Resource Core** to ensure functionality of the entire CART system. The **Data Core** follows the overarching framework of data acquired in the service of capturing vital life domains that best inform AiP. In this framework, the potential for data to be derived across three interacting major technology domains (Monitoring/Measurement (person/environment); Diagnosis or Screening; and Treatment/Intervention (compensation, prevention, enhancement) needs to be maintained. With these goals in mind, **the Data Core aims are to:**

1. **Establish and maintain a complete CART data system** including connected devices and sensors, server(s), software, security, backup and recovery and updating capacities. This aim will be achieved by working very closely with the **Resource Core** which has leading responsibility for the 'front-end', home-based technologies and infrastructure deployment.
2. **Create and curate data standards and metrics** encompassing electronics, sensors, algorithms, clinical measures, and security.
3. **Establish and maintain a secure, yet readily available research Data Repository** that includes person-level records of all captured data, as well as the technical specifications, variable descriptions (data dictionary) and manuals for others to use and build on.
4. **Provide data analytics that incorporates multi-domain sensor data, self-report, health records and other research related data and connect these data to clinical outcomes or outcomes specific to end-user's hypotheses and needs.** In this aim, the Data Core will be responsible for providing statistical analyses for data generated during the development cycles as well as for the **Demonstration Project** (DP). Statistical modeling approaches including programs developed or applied will be shared with the scientific community in a "Repository of Analytical Approaches" to further promote data usage and facilitate advancement of analytical approaches.
5. **Widely share and disseminate data** using a secure, password-protected system compliant with applicable federal data-security standards (including VA and HIPPA) and local requirements. The **Data Core** will be organized to facilitate analysis by many users serving as a CART data, protocols and software clearinghouse linking to other big data and related repository efforts (e.g., Mobile Data to Knowledge (MD2K), NACDA) and the wider research community.

Specific Aims: Data Core

Specific Aims:
The **Data Core** at first principles must be designed to enable the capture and handling of relevant data informing Aging in Place (AiP) research and facilitating subsequent interventions based on that data. Accordingly, as noted in the **Overview** and in the **Administrative** and **Resource Cores**, the **Data Core** will follow the overarching framework of data acquired in the service of capturing vital life domains that best inform AiP. In this framework, the potential for data to be derived across three interacting major technology domains (Monitoring/Measurement (person/environment); Diagnosis or Screening; and Treatment/Intervention (compensation, prevention, enhancement) needs to be maintained. In achieving this goal, data standards are axiomatic for reproducibility and rational evolution of systems and solutions. The delineation of standards not only applies for example to point of care sensor data capture formats, but to the clinical data abstraction and synthesis, and where the two meet. Thus raw digital data may be abstracted generatively to higher levels of clinically relevant conceptualization such as raw accelerometry data being ultimately interpreted as "walking" or being "sedentary". These in turn must be applicable to meaningful and actionable outcomes for research and clinical use. The data at all times must be secure and readily retrievable. At the same time, the processes and health of the systems (from sensors to servers) that provide these data create a set of operations meta-data that also must be accountable. This means that the **Data Core** is a Data *Systems* Core that must provide a resource that comprehensively spans the data needs of CART users. This includes the infrastructure to support the access, collection, encoding, decoding, transmission, processing, storage, analysis, display, and distribution of data. To ensure that the artifacts CART creates (software, data, protocols, etc.), stand as a meaningful guide for future scalable AiP research, ready sharing and dissemination of information and data must be facilitated. Therefore, a secure and user friendly **CART Data Repository** will be key for the desired successful ongoing development of this research for the larger scientific community and other stakeholders.

With these goals in mind, **the Data Core aims are to:**

1. **Establish and maintain a complete CART data system** including connected devices and sensors, server(s), software, security, backup and recovery and updating capacities. This aim will be achieved by working very closely with the **Resource Core** which has leading responsibility for the 'front-end', home-based technologies and infrastructure deployment.
2. **Create and curate data standards and metrics** encompassing electronics, sensors, algorithms, clinical measures, and security.
3. **Establish and maintain a secure, yet readily available research Data Repository** that includes person-level records of all captured data, as well as the technical specifications, variable descriptions (data dictionary) and manuals for others to use and build on. New variables will also be generated to ease end-users' analyses. For example, absent computer usage when participants are out travelling vs. simply no usage when subjects are at home must be distinguished and indicator variables added using other available information to generate this summary variable. These center-generated variables will be created and included in the Data Repository along with person-level records of all captured data (raw data). Our experienced statisticians will liaison across multiple data perspectives (e.g., social scientists, clinicians, engineers) to disseminate the data in the most suitable forms to address end-user's specific hypotheses and needs creating a more effective data dissemination and use process.
4. **Provide data analytics that incorporates multi-domain sensor data, self-report, health records and other research related data and connect these data to clinical outcomes or outcomes specific to end-user's hypotheses and needs.** In this aim, the Data Core will be responsible for providing statistical analyses for data generated during the development cycles as well as for the **Demonstration Project** (DP). Statistical modeling approaches including programs developed or applied will be shared with the scientific community in a "Repository of Analytical Approaches" to further promote data usage and facilitate advancement of analytical approaches.
5. **Widely share and disseminate data** using a secure, password-protected system compliant with applicable federal data-security standards (including VA and HIPPA) and local requirements. The **Data Core** will be organized to facilitate analysis by many users serving as a CART data, protocols and software clearinghouse linking to other big data and related repository efforts (e.g., Mobile Data to Knowledge (MD2K), NACDA) and the wider research community.

Research Strategy: Data Core

1. Significance

Data is the life-blood of CART research. CART will encompass a wide range of data types as well as systems for handling this data and ensuring that it is securely transmitted, stored and disseminated. The current proposal builds on an existing data and information system built for research in a health care environment that interfaces on a daily basis with the community including health care providers, AiP residents, their families and researchers (whether they are collecting data directly in the home, or as outside investigators wishing to use data or gain procedural knowledge). This experience has taught us many lessons. The data system must be able to accommodate growth in data capacity both in terms of storage as well as processing capability. All of this needs to be accomplished in a safe and secure data environment, especially given that much of the data is health-related. For this reason the ORCATECH system we build upon sits behind a firewall specifically designed for operation within a medical or health system context at OHSU. Thus inherent needs for security as found in potentially linking to data contained for example in health records or any personally sensitive HIPPA regulated data are primary considerations for this system. Another important lesson we apply rests with the types of data of interest for CART. Thus, for example, the EHR may contain data of interest, but in the current diverse communities where residents receive their health care from many health systems, the quality (timeliness, veracity), functionality, interoperability or even availability of an EHR may be limited [1-3]. One needs to also augment or *directly* obtain on a more frequent basis relevant AiP data not only about health, but about life activities from the resident herself. Thus a timely personal health and activity record (or PHAR) is of particular value and necessity for AiP research. In order to ensure that the captured data is of most value to ongoing CART investigations *and* the wider research community, the data collected must be from inception recorded in a way that adheres to all current standards while also being poised to be addressable to rapidly evolving data ontologies and new standards of pervasive computing in health care. This means that CART will need to work closely with other ongoing efforts (e.g., Center of Excellence for Mobile Sensor Data-to-Knowledge or MD2K, Continua, industry) to standardize and harmonize the multi-domain expansive data that is generated from many sources. Finally there is meta-data or knowledge about how to conduct AiP research that will be invaluable for building an effective AiP research community. There is a relatively rich experience with regard to conducting research within the aging population per se. However, this is relatively new territory on the technical side, as much prior work has been conducted as small pilot studies with little follow-on linkage to larger field studies and lessons learned. To this end, all protocols (including practical “how-to” videos), algorithms, software and reports will be available to ensure that CART remains a living scalable laboratory.

2. Innovation

In conjunction with the **Resource Core**, the **Data Core** operates and maintains an innovative end-to-end data system that has been designed to meet the key CART needs of technology agnosticism, extensibility and scaling. Thus at the information input level (across embedded sensors, wearables, self-report on-line data) the system accommodates multiple sensors, devices or research designs through straightforward addressability of standard electronics and communications protocols. The **Data Core** is able to maintain the integrity of the systems through the unique Console software enabling low-maintenance remote monitoring of the home platforms and integrity of data capture, as well as updating of software. The system’s storage and processing infrastructure is rapidly expandable and thus readily scales taking advantage of a coordinated architecture of Virtual Machines, storage area networks and Apache Cassandra nodes along with the cluster computing framework, Apache Spark. The data itself is at first principles seen as multidimensional and hierarchical requiring the ability to accommodate multiple current as well as evolving data ontologies and schema. This is important with regard to the innovative Data Repository and sharing structure we propose that is designed to facilitate multiple potential users of different levels of sophistication and need. Drs. Crowe and Dodge, who lead the **Data Core**, are highly experienced in integrating and analyzing large, complex multi-domain data sets with an emphasis on clinically relevant outcomes and analyses. The team will uniquely provide customized data analytic support for data use and dissemination to users of diverse levels of analytic sophistication. The Data Core will co-innovate with established national open data efforts MD2K and the *National Archive of Computerized Data on Aging* (NACDA) to provide the most comprehensive standardized sets of readily sharable clinical, biological activity and behavioral data and related data derived from CART research.

3. Approach

3.1 Establish and maintain a complete CART data system including data capture technology, server(s), its software, security, backup and recovery, updating and means for analysis and data dissemination. To create the data system required we build upon the existing literature, and our over a decade of experience in pervasive computing in the community, the Life Lab and other projects that have mapped pervasive computing and sensing approaches to relevant AiP life domains [4-26]. Thus our starting point is the well established ORCATECH system depicted in **Figure 1** of the **Resource Core** that has been supporting multiple waves of continuous community based deployments for over a decade. In so doing it has had to be built to readily accommodate inevitable advances in technology, software and data requirements. The system is designed to be flexible, redundant, fault tolerant, self-maintained, secure and scalable. It implements virtual machines on Xen servers using a storage area network to run specific tasks such as domain name service resolution, software repositories, and server monitoring. Smaller data sets such as home and subject information are stored in a MySQL relational database while the time series data collected from within the home is stored in an Apache Cassandra (http://cassandra.apache.org/) cluster with Apache Spark (http://spark.apache.org/) running on top as a means to provide for 'big data' analytics. A graph database is also used to store home layouts and sensor locations delineating a personal area network as a means to define possible paths and locations throughout the home (described further in the **Demonstration Project** section).

To ensure proper deployment of software and security settings, a dedicated server runs the configuration management, open source utility Puppet (https://puppetlabs.com/puppet/puppet-open-source). Puppet ensures that the client has the necessary software installed, is up to date, that configuration files are in place and security settings are correct. The use of virtual machines (VM), storage area networks, distributed databases and a configuration management utility allows this system to easily scale and guards against a single point of failure. The primary servers are located and managed by the OHSU Advanced Computing Center at Data Center West or "the Data Dome" completed in 2014 [27-29], a unique leading-edge data center providing high-efficiency redundant systems for power, air conditioning, multi-level physical security, and ample room for growth. All servers are on a continuous rolling backup that is written to tape at a secure physically separate location that can be used to recover the server in case of catastrophic failure. In the event that a Cassandra node would fail the other nodes redistribute the backup data, preventing a disruption in service. The software application Nagios (https://www.nagios.org/) is used to ensure that the system is performing as expected, sending notifications if it finds failures.

The system incorporates the functionality and software needed to remotely manage the data infrastructure and its multi-domain data. As described in the **Resource Core** and **Demonstration Project** section, the software employed (the 'ORCATECH Management Console" or "Console") allows one to not only securely capture the data, but to push software updates to the home, as well as monitor the health of the system itself *in real time* (e.g., battery life, sensor signal loss). Creating this kind of end-to-end adaptive system from scratch would require substantial time, hardware and developer resources beyond the budget of the CART FOA. Our proposal going forward is to efficiently expand on this system as needed, keeping close attention with our advisors and industry partners as to the ongoing needs of the system. As noted, our implementation of VMs, storage area networks and Apache Cassandra nodes in conjunction with the cluster computing framework, Apache Spark, will allow the system to scale as data storage and processing needs increase. Each of these frameworks is expandable through the addition of hardware without reconfiguration. For instance, as the Cassandra cluster grows, a new node can be plugged in and the data is redistributed throughout the cluster to take advantage of the increased space. Also, since all nodes in our cluster are managed with the configuration management utility, Puppet, a new server simply needs to be plugged in, told who it is and the system will integrate it with the correct software and security settings. We project that at current data accrual, storage and distribution levels (approximately 3.3 MB/day/home), this system will scale reliably to at least 1000 homes. For reference, Twitter is estimated to handle 85 GB of tweets per day across its 300 million users [30]. At 1000 homes CART would be approximately 1/85th the size of Twitter in terms of data captured per day; at 10,000 homes CART would be approaching Twitter's current data throughput.

We anticipate that working with the CART Steering Committee, scientific advisors and research community there may be further requirements placed on the system for as yet to be envisioned technologies or data (e.g., if a decision was made to capture and store large amounts of home-based video interviews for a future telecare intervention). To meet demands for further growth the current system can be readily modified by adding a data stream platform such as an Apache Kafka cluster to the system as an abstraction layer between the data producers and various data storage and processing consumers. With this is place we can efficiently add other data processing and storage engines such as an Hadoop Distributed File System on an as needed basis to the system. In addition, Exacloud, an Intel provided and supported high performance computing cluster at OHSU [31] optimized for massive life sciences workloads (e.g. genomics, imaging) would be available to our CART program as needed.

3.2 Create and curate data standards and metrics including electronics, sensors, algorithms, clinical measures, security. In order to ensure that this data system proves generalizable for any future AiP research use cases, this platform (See also **Resources Core** and **Demonstration Project** section) is constructed as a fully featured system using open, standard specifications that are technology "agnostic", i.e., that provide the opportunity to use multiple established or new technologies as long as their basic raw data output is consistent with accepted standards. Key to this functionality is that the sensors or devices as needed adhere to industry electronics standards (e.g., IEEE P11073 – standards; FIMSA; HL7; Continua; NIST [32]) with the data transferred via standard communications protocols (e.g. Bluetooth, WiFI, 3-G, X10, Zigbee, etc.). All data must meet NIST [32] and VA standards at all levels of data capture, abstraction and distribution. Guidelines for these many
standards are too numerous to detail here, but are codified in many NIST and VA published guidelines [33, 34 35].

All data ultimately must map back to our key life domains (physical and mental health, mobility, social engagement, safety, everyday activities and leisure). **Table 1** summarizes the core functions that characterize these life domains and the individual or combinations of sensor sets that will capture the data. Notably, raw data can ultimately be specified at many levels of function. Thus, the system is built upon the principle of accommodating any number of relevant "raw" sensor or data streams from which ultimately one or more sensor outputs can be used individually or fused to determine a particular function or action (see example, **Figure 1**). Specifications must allow for flexible inference analysis across a broad range of potential functional outcomes. Domain descriptions will be set within the major context classifiers commonly used in pervasive computing and developing in open mHealth efforts, e.g., space/location, identity, status/activity, environment and time [36, 37] . Data represented will generally be primary sensor data, clinical data (e.g., scales administered, test results, secured EHR data), and when appropriate, inference results. For example, raw activity counts can be aggregated across a home over time to provide a simple metric of total activity in a day. Or, these counts can be examined by specific location and time and fused with other sensor data to derive such measures as time in various locations [38], walking speed [15, 22], nighttime activity [11, 23] medication taking [24, 39] or device use (phone, computer) [6, 10, 12]. These measured functions in turn can be fused to

Table 1: Core functions and related measures to be collected and types of sensors that can be used to collect those data. Metrics may be event driven (e.g., walking speed) or scheduled (e.g., minutes to days of total activity counts).

Core Function(s) & Measures	Sensors or Devices Used
Physical Capacity/Personal Mobility Total daily activity, number of room transitions, time out of home	PIR motion sensors and contact sensors; Bluetooth beacons and smart watch pairing
Walking speed Median weekly walking speed from multiple daily walks	PIR motion sensor line
Sleep/Nighttime behavior Time of awakening in the morning, time spent in bed at night, wake after sleep onset, times up at night, and sleep latency	PIR motion sensors; Bluetooth beacons and smart watch pairing
Physiologic Health Daily BMI, morning pulse	Biofunction Scale (morning pulse); smart watch (more frequent pulse)
Medication Adherence Percentage of doses missed in a 7-day period, relative to prescribed schedule. (Note that this value will vary.)	MedTracker Electronic Pillbox
Socialization/Engagement Time out of home, time alone or with spouse, phone call patterns, on-line computer activity (email, social network sites)	PIR motion sensors, contact sensors, Bluetooth beacons and smart watch pairing, personal computer, phone monitors
Cognitive Function Time to complete on-line tasks (e.g., weekly PHAR), mouse movements, prospective memory for medication, driving capacity	Personal computer or tablet, MedTracker, Automobile data port telematic sensor
Community Mobility – Driving Time and distance walking out of home; time and distance driving, hard braking, hard accelerations, most frequent locations out of home	Bluetooth beacons and smart watch pairing with automobile data port telematic sensor
Health & Life Events On-line self-report: ER, doctor, hospital visits, home visitors, mood, pain, loneliness, falls, injuries, change in home space, home assistance received, change in medications	Personal computer or tablet

infer particular outcomes and change over time (**Figure 1**). With this in mind the same sensor data can be "repurposed" to identify multiple types of behaviors and function as needed for a specific study depending on the domain precision, or granularity desired, including physiologic change (e.g., body composition), medication adherence, mobility, patterns of sleep and night-time behavior, socialization, and environmental conditions (e.g., home and outdoor temperature, light exposure). The dataset can be richly annotated with common health outcomes and life events by frequent self-report data (ER visits, hospitalizations, falls, visitors, vacations, etc.) and linked to the sensor streams. These outcomes are captured through weekly input from a variety of sources; administrative data (e.g., EHR) and most regularly from the Personal Health and Activity Record (PHAR) self-report via home computer or tablet.

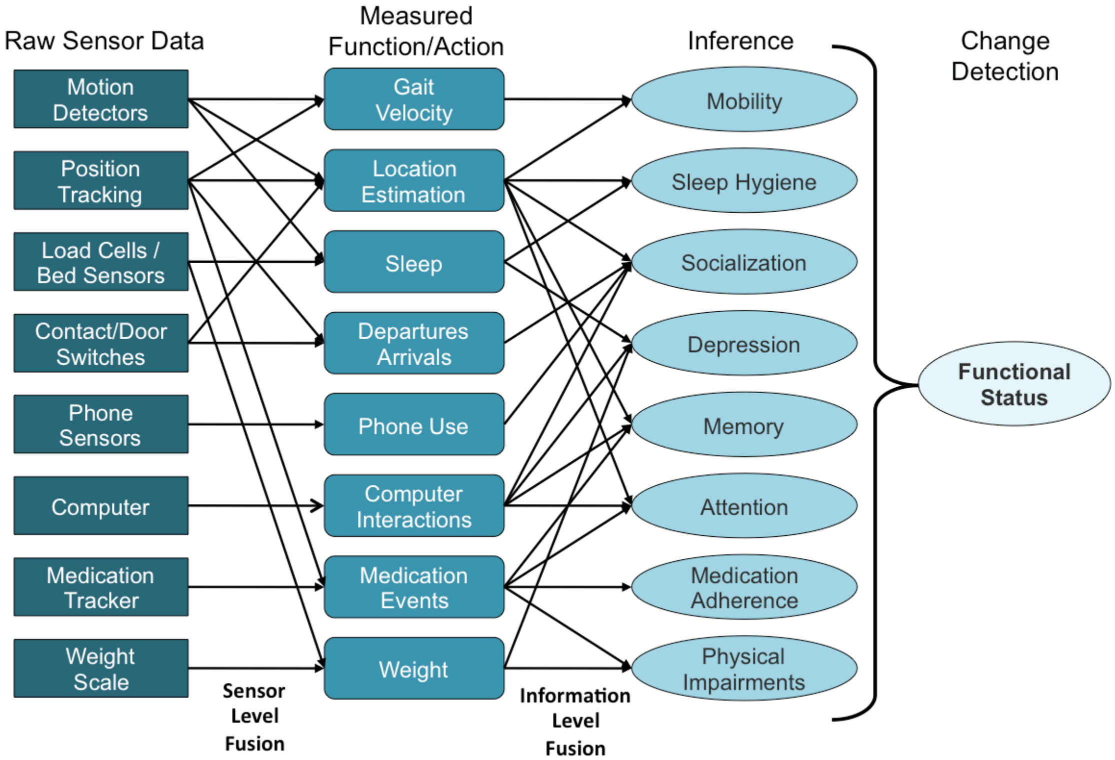

Figure 1. Example of how sensor data is successively integrated to allow extraction of functional activity and inference of important health outcomes.

In all cases all elements must meet initial *functional requirements* set out in a standard format before a project is implemented. For example, in capturing human movement "*a system shall be able to identify and record the location of a specified participant within the home with a minimum room-level resolution of 95% reliability sampled every 5 seconds*". This specification could be met by an IR sensor system, radar system, acoustic system, Bluetooth beacon system, etc. For each technology solution chosen, specifications will be documented in the CART database which generates a library of requirement specifications and the standards used to meet them. (See Appendix; Draft Requirements). Thus, for a particular protocol, the library records, the chosen technology(s) and their specifications (e.g. accelerometer x, recording frequency y, sensitivity z, etc.). Based on this data specification and documentation procedure, we will deploy systems into the CART demonstration development site communities for research [40] .

The process of standards specification and recording does not end with the primary raw or aggregated data collected alone, but also extends to the specification of quality assurance and provenance checking (tracking data through all transformations, analyses, and interpretations) and data system maintenance. This was discussed in the **Resource Core** using the Console linked to the overall database.

3.3 Establish and maintain a secure Data Repository [41].

Data in the Repository. By its nature CART will record multiple classes and types of data. At a high level, data will be recorded with regard to requirements: (1) Program (protocol criteria met, regulatory documentation); (2) Deployed System (e.g., security protocols, installation times); (3) Data Center Systems (e.g., data loss prevention, addressability, device ID); and (4) Research Data (e.g., minimum clinical data, home space mapping, sensor-based data). The Data Repository must accommodate a wide range of primary data types including conventional clinical data as well as sensed data (e.g., **Table 1**). Standard data ontologies that are rapidly growing within the big data scientific community must be followed (these are discussed further below in the **Data sharing** and **Dissemination** section). For current handling of our data in our ongoing studies, we use a relational database structure (MySQL) that captures sensor firings, metadata about activity and changes in the home, provides provenance checking, as well as life events of the subjects, and information about the sensors themselves (See **Figure 2**). This database contains raw data (stored directly from the sensors) and processed data reviewed on a daily basis to identify potential system or data issues. Possible issues are checked by a technician and the data are annotated and issues resolved quickly (approximately 10 instances/week/100 homes with the majority remote fixes). Once data are considered clean, they are aggregated using algorithms developed over the past ten years by us and others, to extract the measures of interest (as previously noted e.g., walking speed, sleep behaviors, activity levels, medication habits, etc.). Process evaluation algorithms are also important for this developmental research. Thus, data are also recorded on the time taken to install the system, to train the volunteers in the use of devices and to monitor the system status using the Console. Measures of efficiency (such as time spent on additional visits or phone calls with the subjects relating to use of, or problems with, the technology) will be tracked throughout using this software.

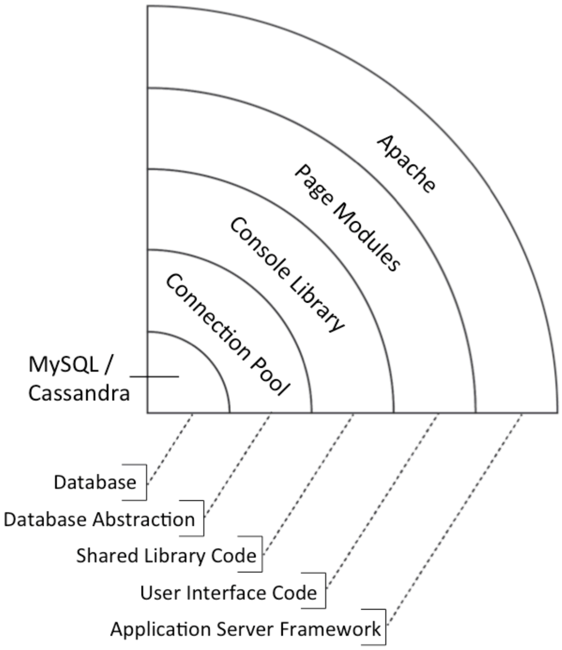

Figure 2. Database software architecture.

A procedurally separate, but equally important data measure is how data which may be further sent or used for clinical interventions is displayed and recorded. Thus for example, the display of clinical function data derived from the sensor data (such as a clinical dashboard) needs to be taken into account. This data in turn needs to be recorded as part of the database. This feedback functionality was presented in the **Resource Core** (see **Resource Core, Figure 6**). All these data are then readily accessible for analysis.

3.4 Provide Data Analytics.

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 [8, 10, 13, 14, 38, 42-44] . 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 as described below.

3.5 Data Sharing and Dissemination.

Data Optimized for Sharing and Dissemination. To optimize data archiving and sharing, it is essential that formats and links that facilitate use and analysis are standard and provide logical search and discovery functionality. These needs are satisfied by conceptualizing the end-to-end loop of data, its capture, transformation into most usable forms, storage, and wide but secure dissemination. Fundamental to this activity is creation and ongoing curation of data flow and ontologies. Many ontologies have been introduced in recent years to address the need for integration of remote sensed data, intelligent agents, web services, and ‘cloud’ computing from hospital care to home-based health promotion. Some of these efforts have been focused on specific domains such as sensors [44] human behavior recognition[45] , or handling EHR or home care records [45]; others have proposed more comprehensive system ontologies and architecture schemata [46-52]. With rapid evolution of pervasive and mobile computing in AiP research, it will be important to further integrate these and other recent developments designed to facilitate data dissemination and sharing in years 2-3.

Highly relevant to CART in this context are the data handling and sharing efforts of the National Center for Biomedical Ontology (NCBO) and the centers of the NIH BD2K (“Big Data 2 [53] Knowledge). NCBO, one of the

NIH National Centers for Biomedical Computing provides tools for development and access of biomedical ontologies allowing the expression of complex relationships in machine-readable form across a wide range of potential CART relevant use cases [54]. This open-source set of tools will be critical for ensuring that the diverse CART data conform to standard biomedical ontologies specifically relevant to AiP. Especially germane is the BD2K trans-NIH initiative launched in 2012 to advance the ability to harvest the wealth of information contained in biomedical big data by creating needed tools and data accessibility. Among BD2K centers particularly important to CART is the *Center of Excellence for Mobile Sensor Data-to-Knowledge (MD2K)* [55] and the affiliated Open mHealth organization, a nonprofit start-up dedicated to creating open source tools and services for the mHealth community [56]. We have discussed with Dr. Kumar, leader of the large MD2K consortium, plans for collaboration (see support letter) including the potential integration of our data schema with the developing MD2K approach; we are readily aligned with one another. Notably, our current framework where we routinely pass JSON objects between our clients and servers facilitates the ability to translate and align within the evolving Open mHealth framework to standardize objects and overall data ontologies.

Because of the rapidly developing standards and analytics work represented by such efforts as MD2K, the Open mHealth group, ORCATECH, VA, industry and others, we anticipate working closely with these colleagues especially in years 1-3 to incorporate these developments as they continually evolve. It will be important to follow and integrate these efforts with those that have already been put forward and more specifically align with the needs of the AiP and independent living community. With this in mind, during the first year of our proposal, we will complete a systematic review of these ontologies in collaboration with the many important stakeholders that need to be involved in this effort (industry, academic researchers, health care providers, resident end-users) with the express purpose of creating an AiP focused schema for the field.

Dissemination. We emphasize that the data are designed to be archived and posted so as to be maximally useful for the wider research community. A CART website link will provide instructions to honor requests either in a “self-serve” mode (basic de-identified datasets available with minimal annotation) or a data “concierge” assisted mode for more complex requests. In order to also assist in growing the national research enterprise that can use the methodology that is established, platform specifications, as well as “how-to” tutorials will be recorded and posted on the website under “CART Tools”. The latter will include step-by-step annotation for setting up platforms in a series of homes across diverse communities. This narrative will be facilitated by the need to do this for our initial build out to all sites; the development of years 2-3 incorporates this goal (see DP). Finally a “Repository of Analytical Approaches” will make available the data analysis routines used by CART.

Several NIH-supported efforts are engaged in archiving health related data for wider use. Highly relevant in this context, is the *National Archive of Computerized Data on Aging (*NACDA*)* preserves and makes available the largest library of electronic data on aging in the United States [57]. ORCATECH has previously archived at NACDA a de-identified pervasive computing-based activity dataset *(*“Daily In-Home Activity Metrics from the Intelligent Systems for Assessing Aging Changes (ISAAC)” study - ICPSR #35063 [58]. Since being released in June, 2014, over 120 unique users have downloaded files indicating high interest in these kinds of data. We will continue to work with NACDA and Dr. James McNally, NACDA Director (see support letter) to deposit useful datasets to the aging research and general community. Thus we plan to make available through our CART Data Repository primary, minimally processed or ‘raw’ data (typically for more advanced users), as well as metadata about the process and procedures for conducting this research. At the same time, we will collaborate with NACDA to provide archival datasets with many aggregated variables of interest (e.g., time in bed, time out of home, walking speed) to the aging community. In this way our intent is to provide an efficient set of resources that is customized to the wide range of potential customers of the data that will be available from CART. *At all stages, storage and report out from the Repository will use secure, password-protected systems compliant with applicable IRB and federal data-security standards including VA requirements* [41].

Finally, it is important to consider that although much CART emphasis is understandably on functional assessment and intervention, an important additional set of data elements in the domains of biological or biomarker data will available. Many of the volunteers to be engaged in our CART proposal also have or will be asked to consent to provide a blood sample (supported through the OHSU Biomarker Core of the OHSU Alzheimer’s Disease Center; P30AG008017) for DNA and blood biomarker data that is highly relevant to studies of independent aging (e.g., ApoE genotype). Thus we emphasize that we will need to link to a number of national and international database and data specification efforts that are relevant especially to future considerations of linking dynamic quantitative CART phenotypic data to these kinds of biomarker data.

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Budget Justification: Data Core

Data Core A. PERSONNEL

Hiroko Dodge, PhD *Co-Investigator and Data Core Co-Lead (0.96 calendar months per year)*
Dr. Dodge is Associate Professor of Neurology at OHSU and director of the Data Core of the NIA - Layton Aging & Alzheimer's Disease Center (which provides the clinical database for ORCATECH studies such as in the current proposal). Along with Dr. Crowe and Ms. Mattek (see below), she will oversee the direction and coordination of all aspects of data handling from entry to analysis. All papers emanating from the proposed research will be reviewed by Dr. Dodge for appropriate design and accuracy. Her expertise includes study of longitudinal trajectories of independent activities of daily living and cognitive functions over time, cross-national comparisons and predictive values of neuropsychological tests, novel cognitive measures, age-associated declines in leisure activities, and clinical trials. She recently completed as PI the first RCT using home-based technologies and monitoring to assess and encourage social engagement in older adults with MCI or at risk for MCI, and as such has an exceptional understanding of the strengths and limitations of the kinds of data to be collected in the CART initiative.

Kathleen Crowe, PhD *Co-Investigator and Data Core Co-Lead (1.2 calendar months per year; in-kind)*
Dr. Crowe is Director of Data Science and Applied Analytics, DCG Big Data Solutions, Intel Corporation, Hillsboro, OR. Dr. Crowe will work closely with Dr. Dodge and will be responsible for oversight of the data systems, large data analytics and data back end of our CART proposal. She has extensive training and experience in leading academic and commercial scientific and analytics projects, spanning core research in mathematical biology, applied analytics projects in multiple disciplines, and the development of software and technology capabilities to put these solutions in production. As a research mathematician, she conducted individual and team-based studies in the areas of population dynamics and mathematical ecology, and participated in research planning and study design both at home and internationally. Since moving into the commercial world Dr. Crowe has developed and led the development of software solutions for large-scale analytics, led efforts in providing actionable analytics solutions in multiple verticals (health and life sciences, financial services, internet of things, etc.) and led the design of analytics and data science requirements for a cloud-based distributed analytics platform. Given this array of experiences, she has a broad-ranging skillset, encompassing software development, large-scale analytics, and applied problem solving. In addition, much of her experience has involved interdisciplinary work in which she played the role of translator, making sure that people with divergent backgrounds (e.g., ecology and mathematical optimization) were communicating and understanding each other.

Data Core B. OTHER PERSONNEL

Robin Guariglia *Data Manager and Research Associate (3.12 calendar months in Year 1; 4.8 calendar months Years 2-4)*
Ms. Guariglia has managed the Data Management and Statistics Core for the Oregon Alzheimer's Disease Center (AG008017) for over a decade. She has experience in creating extensible database structures, data collection forms, report formats and information transfer protocols. She will be responsible for coordinating data acquisition, implementing database design modifications, and other administrative functions such as maintaining current documentation, training staff and investigators in the use of the database, and performing security procedures. She has experience serving as the main liaison with key stakeholders for the OADC, including the National Alzheimer's Coordinating Center and National Cell Repository for Alzheimer's Disease. Her experience makes her well suited to serve as the CART Data Manager.

Thomas Riley *Technician Research Assistant (1.2 calendar months Years 1-4)*
Mr. Riley is ORCATECH's Technical Lead and a Research Associate with over eight years of experience in monitoring, trouble-shooting, and maintenance of the technologies deployed into ORCATECH studies. He will be responsible for monitoring the day to day collection, backup and storage of the data. He will identify and resolve issues relating missing data and data anomalies. Mr. Riley has been instrumental in the management and development of the current software tool – the ORCATECH Management Console - used to manage all ORCATECH cohorts, including over 300 active subjects. This tool allows secure, remote management of cohorts (e.g., tracking adherence to completion of questionnaires, including weekly questionnaires, tracking

upcoming in-person evaluations, tracking health issues), as well as the in-home systems themselves (e.g., tracking device inventory, sensor "health", and data reliability, as well as supporting remote fixes of problems). He will also be responsible for the establishment of the technical aspects of the CART Data Repository. There have been many lessons learned over ORCATECH's 12 years, and Mr. Riley's expertise in providing iterative systems management for in-home systems at multiple levels will be crucial to continuing to evolve and advance the data management tools needed for CART.

Nora Mattek, MPH *Associate Statistician and Research Associate (1.2 calendar months Years 1-2; 3 calendar months Year 3; 3.6 calendar months Year 4)*
Ms. Mattek is a masters-level statistician who will be responsible for review, cleanup and annotation of CART data, and for developing integrated statistical models. She has three years' experience working with and cleaning up ORCATECH data, as well as assisting PIs in abstract and manuscript development. She will work with the PD/PI's, and with Dr. Austin (analyst/algorithm developer, see below) examining CART study outcomes, during the V1.0 and V2.0 development cycles of CART and during the Demonstration Project. She will also work to understand limitations of the data, what cleanup is needed, and how to interpret outliers. In addition, she will perform ongoing interim summary analyses of the developmental data in years 2 and 3, producing data summaries and identifying data sets that are appropriate for dissemination. She will be responsible as the first line data concierge, providing customized help to potential users of the data in the later years of the grant. Finally, she will be a liaison with the National Archive of Computerized Data on Aging (NACDA) where we intend to deposit clean useful anonymized data sets and protocols for sharing with the research community.

Mattie Gregor *Research Associate (2.4 calendar months Year 1; 7.2 calendar months Year 2; 9.6 calendar months Years 3 and 4)*
Ms. Gregor is a resarch associate with four years of experience working with ORCATECH, with particular skills in recruitment and retention of volunteers, data management and quality assurance. Ms. Gregor has extensive experience working with the Console and developed a standardized system for coding weekly PHR data (what will be the Personal Health and Activity Record (PHAR) in the CART proposal) to facilitate analyses of this frequent self-report data. She will be responsible for following up on the weekly PHAR responses from participants at all four demonstration project sites. She will monitor and respond to changes in health status indicated on subjects' weekly health questionnaires, contacting subjects to gather additional information as necessary (e.g., conduct an interview about fall events). Given the complexity of the coding system and Ms. Gregor's experience, these responsibilities are best centralized for all four sites in the Data Core. We request increasing support for her effort over the grant as the number of enrolled participants increases. Based on our experience with other ORCATECH cohorts, we estimate that follow-up on weekly health forms requires about 4 hours per home. For 360 participants in a fully-enrolled CART over all four sites, we have budgeted 9.6 calendar months for her time (4 hours x 360 participants = approximately 1,500 hours or 0.8 FTE).

Data Core C. EQUIPMENT

C.1. Servers: We request funds for hardware server purchases to support the data needs generated by CART sites and subsequent data-related activities. At an estimated 3.3 MB per day per home with 240 homes, our Cassandra cluster would need to expand by 4 nodes to process and store the 1.1 TB generated by the CART sites. In addition, the increased load on our configuration management software generated by CART's 240 in home hubs necessitates purchasing a dedicated machine capable of handling and processing numerous simultaneous anticipated data requests. The exact hardware requirements will be determined by the Data Core leaders and other appropriate advisors based on the best solutions and equipment available at the time of purchase (given the rapid evolution of this area over a year or more into the future we must adopt a position of flexibility). Based on previous purchases and market prices each Cassandra node will cost approximately $3,500 and the configuration management server will cost approximately $6000. For these reasons we request $20,000 in Years 1 and 2. We have examined other alternatives such as commercial "cloud" management options (e.g. Amazon Web Services), but these do not necessarily provide a clear advantage at this time balancing, costs, security, high data processing needs (separate from simple storage) and customization considerations. We have the ability to tap into the Exacloud High Performance Computer cluster supported by Intel at OHSU if this emerges as an need in subsequent years (see Data Core).

Data Core D. TRAVEL: None

Data Core E. PARTICIPANT /TRAINEE SUPPORT COSTS: None

Data Core F. OTHER DIRECT COSTS

F.1. Materials and Supplies: None

F.2. Publication Costs: None

F.3. Consultant Services: None

F.4. ADP/Computer Services:

F.5. Subawards/Consortium/Contractual Costs: None

F.6. In-Kind Contributions: Intel Corporation is contributing Dr. Crowe's time.

Summary: Demonstration Project

Our proposed **Demonstration Project** (DP) serves to provide meaningful evidence for the feasibility and utility of our CART system to move to Phase II CART research. The DP is designed as a feasibility study of the technology system, while also assessing the DP as a primary Aging in Place (AiP) research study, testing whether the CART system measures and detects maintenance of independence and/or functional declines and transitions leading to greater dependency. Our DP hypothesis is that *the AiP metrics derived from the technologies employed in our DP are capable of measuring and predicting loss of independence or its risk profile*. The CART DP is based on the existing ORCATECH platform that was specifically designed to facilitate AiP research in real world community settings. The iterative CART system will be developed using well-established processes of the systems development life cycle and user-centered design, applied across four cohorts representing 360 AiP residents who are particularly challenged to remain independent. These include the oldest old with chronic disease, veterans living in rural communities, minorities (African American and Hispanic) and socially isolated seniors of low income. **With these considerations in mind, our aims are to:**

1. **Establish the basic CART platform and research infrastructure, “CART V1.0”.** This will entail design and analysis of the optimal system for initial deployment starting with the basic ORCATECH platform and focusing on the challenges that may be faced in implementing technology-related research functionality in older populations most challenged to maintain independence.
2. **Prepare and deploy the CART V1.0 system to our four CART sites.** This aim focuses on preparing the CART sites and technology (training, setting up the technologies in homes, establishing optimized use by the research participants and research teams, etc.). The sites, chosen for their research expertise and diverse cohorts, are readily available for AiP research and will test this initial system leading to a second major phase of development of CART V2.0.
3. **Iteratively, optimize and add needed functionality to the system in subsequent versions of the platform to result in a final CART V2.0 for the Demonstration Project.** This includes improving our capacity to identify unique behaviors of individuals in a dyad, assessing out of home activity, and developing an instrument to proactively assess scalability, the Scalability of Technology in Aging Research Tool (“START”).
4. **Deploy and test the full CART V2.0 system in the Demonstration Project in year four.** This aim is geared towards testing the hypothesis that the AiP metrics derived from the technologies employed are capable of measuring and predicting loss of independence or its risk profile.

Specific Aims: Demonstration Project

Our proposed **Demonstration Project** (DP) serves to provide meaningful evidence for the feasibility and utility of our CART system to move to Phase II. Further, conducting the DP establishes the value of the system for Aging in Place (AiP) research. It is evident from the FOA that Phase II is appropriately not yet fully proscribed as to its specific scope and aims, beyond facilitating research toward such goals as "to help reduce hospitalizations, emergency room visits, and admissions to a nursing home". This reflects that much will be learned in Phase I to guide the next research chapter. However, to most effectively guide the development of the DP where success ultimately will be measured by how well the CART system facilitates Phase II AiP research, certain assumptions must be made. Accordingly, the CART system we propose is designed to be ready to integrate into several potential Phase II scenarios that include (but are not limited to) application toward public health guidance, care management in various retirement settings, and clinical trials. A common denominator of AiP outcomes for each of these scenarios is that the system needs to be able to capture meaningful functional life activities across diverse populations and contexts. We will thus conduct the DP as a feasibility study of technology, **and** operate the DP as a real world research study. This will enable us to test the central question of whether the CART system measures and detects maintenance of independence or the flip side, functional declines and transitions to higher levels of care need and to greater dependency. Thus the DP hypothesis that we propose to test is that *the AiP metrics derived from the technologies employed in our DP are capable of measuring and predicting loss of independence or its risk profile*.

With these goals in mind, we constructed the CART DP upon the existing ORCATECH platform that was specifically designed to facilitate AiP research in real world community settings. Basic domains of function are identified with a core set of metrics (augmented by secondary variables and conventional clinical data) that are integral to independent aging. This is our starting point. Using CART **Resource** and **Data Core** assets we then iteratively evolve over years 1-3 an optimized CART infrastructure using the systems development life cycle (SDLC) process and user-centered design principles that leads to the DP of year 4. The process takes advantage of the flexible nature of our platform to build additional desired functionality based on the expertise of our research team and advisors. We have identified several key areas that are potential bottlenecks to scalable AiP research that over the course of the CART research program will be addressed. These include the ability to specify with precision the in-home activity location of a particular person when there is more than one person present, the ability to assess mobility outside the home including driving (also a cognitive task), and improving the process of deployment itself. We emphasize that we anticipate possible additional or alternative functionality being added based on the input of the Steering Committee and other advisors as the research and technology evolves. The iteratively developing CART system will be tested using well-established processes of the SDLC and user-centered design, applied across four research cohorts representing 360 AiP residents who may be particularly challenged to remain independent. These include the oldest old with chronic disease, veterans living in rural communities, minorities (African American and Hispanic) and socially isolated seniors of low income. **With these considerations in mind, our aims are to:**

1. **Establish the basic CART platform and research infrastructure, "CART V1.0".** This will entail design and analysis of the optimal system for initial deployment starting with the basic ORCATECH platform and focusing on the challenges that may be faced in implementing technology-related research functionality in older populations most challenged to maintain independence.
2. **Prepare and deploy the CART V1.0 system to our four CART sites.** This aim focuses on preparing the CART sites and technology (training, setting up the technologies in homes, establishing optimized use by the research participants and research teams, etc.). The sites, chosen for their research expertise and diverse cohorts, are readily available for AiP research and will test this initial system leading to a second major phase of development of CART V2.0.
3. **Iteratively, optimize and add needed functionality to the system in subsequent versions of the platform to result in a final CART V2.0 for the Demonstration Project.** This includes improving our capacity to identify unique behaviors of individuals in a dyad, assessing out of home activity, and developing an instrument to proactively assess scalability, the Scalability of Technology in Aging Research Tool ("START").
4. **Deploy and test the full CART V2.0 system in the Demonstration Project in year four.** This aim is geared towards testing the hypothesis that the AiP metrics derived from the technologies employed are capable of measuring and predicting loss of independence or its risk profile.

Research Strategy: Demonstration Project

1. Significance

The ultimate goal for our proposed Demonstration Project (DP) of CART is to be ready to conduct large-scale Phase II research that addresses key outcomes relevant to AiP such as reducing hospitalizations or nursing home admissions. This research will take several innovative directions that the CART system needs to be ready to address. These include, but are not limited to, application toward public health guidance, care management in various AiP or retirement settings, and clinical trials. We have been active in these areas and plan to integrate major principals in them to further inform our DP so as to be ready to quickly deploy Phase II projects in these major research domains. For example, Dr. Kaye, has recently been commissioned to prepare a review for the NIA Health & Retirement Study (HRS) addressing the future of objective health measurement using sensors, technologies, and devices, and what the HRS should be considering for future incorporation in their longitudinal panel study. The 20,000 person HRS sample could present a unique opportunity to transform how the HRS explores the changes in labor force participation and the health transitions that individuals undergo toward the end of their work lives and in the years that follow (see support letter). Similarly, we appreciate the application of CART to provide evidence for the efficacy of a variety of interventions on a large population management basis that for example may be found in organized retirement communities or in less formally organized low-income housing settings. In this scenario, we can foresee deploying the CART scalable system in large community management projects such as among the millions of residents in retirement community settings (see support letter, LeadingAge CAST) or to create or build upon specific intervention programs such as the Experience Corps (see support letter). Finally, we also realize the potential of CART methodology to transform clinical trials [1, 2]. Since the most meaningful outcomes for treatments targeted toward conditions threatening AiP must demonstrate improvement or maintenance of everyday function, this provides the opportunity to conduct clinical trials where the CART system provides outcomes that are ecologically valid and inherently most meaningful. Thus, we envision wide use of the CART system in a range of high impact clinical trials of older patients with conditions such as heart failure, Parkinson's disease, MCI or the 800,000 living alone with Alzheimer's Disease in the U.S. (see support letter from the Coalition Against Major Disease) where the primary meaningful outcome measure for example would be delaying transition to higher levels of care need or successful AiP.

2. Innovation

We include several important innovations in the process of developing the systems and technology leading to the DP and in the conduct of the DP**. First,** during the cycles of development building to the DP, we create a new multifunctional, technology impartial or 'agnostic', and scalable system for AiP research. **Second**, the process involves engaging four geographically dispersed, socioeconomically, health, and independence challenged diverse participant cohorts that have rarely been engaged in this kind of research even at this medium scale level. These aspects of our approach are notable, directed to be technology agnostic, and disease or condition agnostic such that the system is designed to be able to assess across the major domains of function (physical and mental health, mobility, social engagement, safety, everyday activities, and leisure), that collectively are critically important for AiP research as opposed to more narrow use cases such as more continuous physiological monitoring or a care management application. Indeed, we incorporate the ability to conduct the latter more specific use cases if desired. **Third**, we address the need to unambiguously understand in particular the activity and behavior of two co-residents as unobtrusively as possible using a novel application of a multifunctional Bluetooth beacon - smartwatch system. This provides the ability to generate novel caregiver metrics (e.g., change in time spent together in the bathroom or bedroom). **Fourth** we will employ the same wearable system to determine out-of home activity and behavior most relevant to AiP. In this innovation, advancing out of home assessment of independence, we provide the ability to identify patterns of both pedestrian activity, as well as driving behavior with the latter assessment accomplished using a telematic device that queries the data port of the participants' automobiles. **Fifth,** we systematically harness the accumulated results of the longitudinal CART data and experience of both the participants and the research teams to create a novel Scalability of Technology for Aging Research Tool (START). This user-centered, data driven, new tool will greatly aid in the planning and guidance needed in development and deployment for all who plan to develop future AiP technologies. These innovations and lessons learned are rigorously assessed by testing a fundamental AiP research hypothesis directed at whether the developed CART system is up to detecting signal changes of AiP during the DP. Finally, throughout every step of the research process we engage multidisciplinary teams applying research strategies incorporated from industrial research and development, user-centered design, and big data analytics.

3. Approach

3.1 Establish the basic CART platform and research infrastructure: "CART 1.0"

As noted frequently in this proposal we anticipate fast tracking development based on a number of factors. First, we have over a decade of experience in creating, deploying, maintaining, revising, and sustaining an AiP research system through our ORCATECH work in collaboration with many partners in academia and industry. This system has been highly accepted by seniors living independently in the community. The attrition rate due to no longer wishing to participate across all monitored cohorts for the past 5 years has been < 3% per year. This "battle-tested" system will be our starting point. Second, we take an industrial science view of life cycle development in formalizing the needed platform optimization process leading to the year 4 DP. Finally, we take advantage of an experienced, multi-disciplinary team of clinicians, human factors experts, behavioral scientists, engineers, business executives, end-users, and computer and data scientists, most of whom have been working together in this research space for many years.

Core Measures and System. The overall system for capturing, recording, storing and reporting data has been described in the **Resource and Data Core** sections (see also **Resource Core, Figure 1**). These Cores will be responsible for build-out and revision of the platform throughout the project. As noted, this system is designed to provide objective relevant life metrics focused on domains of function abiding by the principle of maximizing

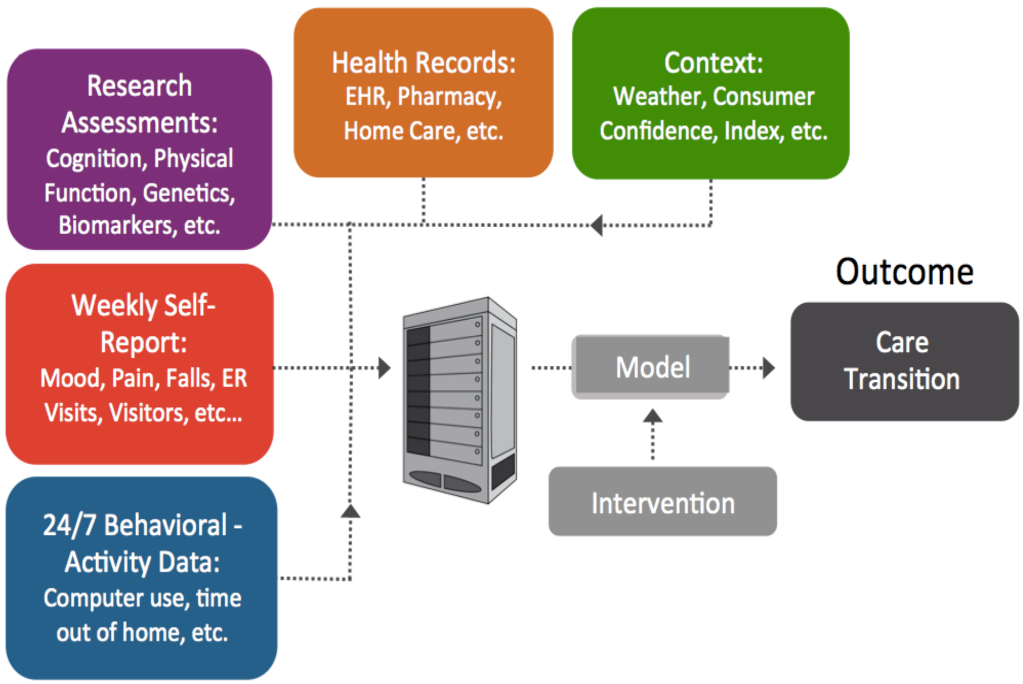

Figure 1. Schematic diagram of the multi-domain data model used to predict care transitions (indicative of ability to AiP) either as a surveillance risk model or to test the effect of an intervention. Data inputs provide: external context (e.g., daily weather data from publically available NOAA); health records, (e.g., EHR's); research assessments (e.g., psychometric or physical function tests, imaging or biomarker data); on-line weekly self-report (e.g., medication change, hospitalization); and in-home sensors or devices (e.g., walking speed, sleep behaviors)

unobtrusiveness wherever possible and generating actionable data. The field of health technology has tended to focus on somewhat narrow applications such as a single wearable device or app. Although there are certainly instances proven highly useful, such as classic telemedicine, we also need to ensure that our research is forward projecting to encompass the growing "Internet of Things" where greater scalable value and in many cases statistical power is to be found in being able to accommodate multi-domain data. In this light *the system is designed to provide a broad range of inputs for high dimensional data models that provide higher levels of accuracy than possible with sparse data* (See **Figure 1**). For example, preliminary analysis using this kind of model to predict transition to a higher care level within 6 months yielded an AUC of 0.98 under the ROC curve (Data: 51,460,018 samples across domains collected from 91 participants over 2 years) [3].

We routinely record and regularly report a basic core set of measures: Physical capacity and mobility (in and out of home movements), sleep and nighttime behaviors, physiologic (BMI, morning pulse), medication-related (adherence), social engagement (email, telephone use), cognitive function and a range of self-report health and life events (ER-, doctor-, hospital visits, home visitors, mood, pain, loneliness, falls, injuries, change in home space, home assistance received, change in medications) (also summarized in the **Data Core** in **Table 1**). The core metrics are standardized and routinely passed as JSON objects directly in our database enhancing performance, as processing the data before sending it can slow down loading and downloading times. These data are then available in multiple formats for the research team, formal and informal care providers, or other individuals as raw sensor data or summarized for example in spiral plots or line graphs on activity dashboards (see the **Resource Core**). Our goal is to make the data as useful and usable as possible to a broad range of consumers.

3.2 Prepare and deploy CART V1.0 to the four CART sites.
A major test of any scalable system resides in the ability of teams at multiple sites to be able to replicate the process of deployment and maintenance remote from a central site experienced in the process. Based upon experience in deploying these technologies in prior large-scale operations (e.g., the Home Based Assessment Study [4] where we deployed computer and MedTracker devices to 26 cities in the US for 200 subjects enrolled for up to 4 years, we have many lessons learned to build upon. Thus we prepare for the first phase of development leading to the DP by training for deploying the CART V1.0 platform to 4 diverse sites.

The CART Development Cohorts. Before describing the initial process of deployment (which will involve training and other procedures) we describe the unique cohorts and the rationale for engaging them for the DP. Many pilot studies and proof of concept studies have shown promising results of many technologies. However, almost all of these have been conducted with small samples, lacking ethnic or clinical diversity and with brief or no follow-up [5]. The few published large scale studies that have involved more general populations have been limited to telecare or telehealth as opposed to more holistic pervasive computing platforms. Thus to advance the field, (and certainly for Phase II study) we need to address these shortcomings. We therefore have chosen our research cohorts to provide more stringent tests of feasibility by virtue of our recruited individuals representing aging scenarios that are likely to most challenge the use or integration of AiP technology. These are individuals who are known to face the greatest risk of losing independence by virtue of their advanced age, isolation, medical or health conditions, or socioeconomic status.

With these principles in mind, we propose to enroll 360 AiP residents who may be considered as particularly challenged to remain independent. The CART participants will be distributed across four complementary but diverse cohorts at four sites: octogenarians living in section 202 housing with chronic disease (Portland, OR), veterans in rural communities (Northwest US), and minority older adults (African Americans and Hispanic elders) in Chicago, IL and Miami, Fla. Each site will ultimately enroll 60 homes (or 240 in total). Given the demographics and the focus on those at highest risk for loss of independence, half of the volunteers will live alone (120 homes) and half will live with a spouse or family member. In the latter case, both household members will be considered research participants. Overall inclusion criteria include being age 65 or older living alone or with a spouse/partner in a larger than one-room apartment; not demented [6]; and age and education adjusted Mini-Mental State Examination (score > 23) [6]. Conditions that would limit physical participation at entry (e.g., wheelchair bound) or likely lead to untimely death over 36 months (e.g., certain cancers) are exclusions. Characteristics of the volunteers by cohort and the unique circumstances they bring to this research are described below.

Octogenarians with low income: This cohort will be focused on those ≥ age 80 of low-income status who are at high risk for transitions to higher care levels. These individuals will be recruited from the Portland metro area from the Union Manors section 202 housing communities (581 units; 564 residents; 75% women; 51% representing minorities; 43% live alone; 30% drive; http://theunionmanors.org/kirkland-union-manors/; (see support letter). In addition, we will also draw from an existing pool (n=130) of ORCATECH octogenarian volunteers (NIA P30AG024978; J. Kaye, PI) already identified who are of low income, largely female (73%), living alone (75%), with 20% minority representation, and > 50% with two or more chronic conditions. Only low-income individuals will be included from this cohort. This cohort will be provided the extensive clinical characterization with standard clinical and biomarker measures of the Life Lab [7] through the Roybal Center (at no additional cost to CART) facilitating the addition of detailed cognitive and other clinical measures included in the Uniform Data Set of the National Alzheimer's Coordinating Center (similar to the MARS cohort below). Dr. Kaye will be the site PI for this cohort.
Veterans: These participants will be recruited from the Veterans Integrated Service Network 20 (VISN 20; Northwest region comprising 1.1 million veterans, 41% in rural areas) who are over age 65, have a neurodegenerative disease (such as Alzheimer's or Parkinson's disease) and currently receive care via the ongoing VA Clinical V-Tel (CVT) telemedicine program. These individuals (currently a total of 637 CVT patients) have difficulty traveling to specialty clinics for face-to-face care due to distance or disease specific limitations. Participants will be primarily couples living together in rural communities. Because these couples live in remote communities and have a partner with a significant disability, they are at high risk for needing

higher levels of care. The cohort will consist of largely female caregivers of a male veteran with a chronic neurological condition. This population receiving care through the specialty neurology clinics with CVT have available extensive clinical and socio-demographic data in the VA EHR. Dr. Erten-Lyons, lead for Neurology CVT Dementia Telemedicine will be the site PI for this cohort.

Urban African American seniors: These participants will be recruited from the Minority Aging Research Study (MARS; R01AG22018; L. Barnes, PI), a longitudinal cohort study established in 2004 in Chicago at Rush University Medical Center which follows a cohort of over 500 African American seniors to study cognitive, motor and related change with aging [8] . The cohort has been extensively described and consists of individuals of mean age 78 (range 64-101), 78% women, 63% living alone, 15 years (mean) of education, with high rates in particular of vascular risk factors (34% diabetes, 84% hypertension); 48% with at least 2 vascular diseases overall (e.g. MI, heart failure, claudication). Twelve percent live in section 202 housing. They are at high risk for incident health events putting further stress on the ability to AiP. They are extensively clinically phenotyped [9, 10]. Dr. Barnes will be the site PI for this cohort.

Diverse socially isolated seniors of low income: These participants will be recruited from the PRISM (Personal Reminder Information & Social Management System) trial cohort (n=300) a major study of the NIA Center for Research and Education on Aging and Technology Enhancement (CREATE; P01AG17211; C. Czaja, PI), a consortium of three universities (University of Miami, Florida State University, and Georgia Institute of Technology) focused on developing and evaluating interventions and design solutions to promote successful technology adoption among older adults. The PRISM study (S. Czaja, PI) began in 2011 and is based at the University of Miami [11]. The cohort is mean age 76 years, 78% women, 42% minorities (African American or Hispanic), and 87% are below the median US household income for those age ≥ 65 years. This cohort is unique not only in the implications of their demographic profile for AiP study, but also in that half will have been randomized to PRISM, a computer-based intervention designed to support social connectivity, memory, skill building, and access to community resources. This provides the opportunity to pilot the effect of incorporating a new system (CART) into a cohort experienced with the established (PRISM) home technology. Dr. Czaja will be the site PI for this cohort.

Clinical Data and Assessments

The sites are diverse, representing a wide array of life scenarios and contexts. This is desirable for determining if the technologies are to be generalizable and integrated into a variety of current or future research studies. However, a common core of clinical data must be captured to enable comparative research. In some cases commonality will be assured by the nature of the ongoing data collection (e.g. Life Lab and MARS cohorts both collect the Uniform Data Set of the National Alzheimer's Coordinating Center [12]). Common subject core measures selected for this CART demonstration are based on what the cohorts already have available, as well as additional items critical for the research. Each site team will be responsible for collecting this data at entry; in several cases there are comparison equivalents that can be used. With this in mind, the battery covers the following domains: 1) Demographics (age, gender, education, marital status, race/ethnicity, household income, occupation); 2) Health history (TBI, hypertension, diabetes, heart failure, MCI, medications, etc.); 3) Physical function (blood pressure, visual acuity, hearing, timed walk); 4) Habits (smoking, alcohol, exercise, leisure, driving); 5) Social network; 6) Cognitive screen (MMSE) and z-score normalized cognitive battery composites; 7) Depression (GDS) and Loneliness (UCLA scale); 8) IADL (FAQ); 9) Formal Care and Services Utilization [13]; 10) Functional health and well-being (SF-36[14]); and 11) Technology experience and proficiency (Technology Experience and Proficiency Questionnaires, CREATE).

Procedures

Overview – Core Components: A basic platform of sensing technology forms the backbone of the overall system for capturing continuous unobtrusive home-based data. The overall platform was described in the **Resource** and **Data Cores**; further elements of this platform are described here. The core platform is flexible (elements may be added or removed) based on the information obtained during the process of gathering user attitudes and beliefs data specific to the research questions and outcome measures of interest.

Plug PC and Ethernet Connection Data Hub: A Plug PC (a monitorless CPU; Dreamplug, Globalscale, Anaheim, CA) and Ethernet connection allow data collection from the system devices and transmission back to our secure servers at OHSU without participant interference. The Plug PC is configured to the specific participant and home set-up upon system installation using a laptop and a centralized digital participant management system. Additional data collection devices (such as sensors, phone monitor, MedTracker and scale) are configured by communicating with the Plug PC.

The Console - Centralized Digital Participant and Remote Technology Management System: A custom technology and data management system (the "Console") allows participant home configuration and system set-up, as well as ongoing remote technology management of homes including secure data collection and monitoring. To facilitate deployment of the system in the community where each home may have a unique layout, a graphing tool based on a tablet interface is used to automatically record in the home the location of sensors and their valid physical adjacencies to other sensors (**Figure 2**) creating a personal area network (PAN) diagram. This is important for reference during remote monitoring of the system at the home level.

Infrared Motion Sensors and Zigbee USB Dongle: NYCE Sensors (NYCE, Vancouver, BC) are digitally assigned to a given home during system installation, communicating with the Plug PC via a wireless Zigbee USB Dongle (ETRX3USB, Telegesis, Buckinghamshire, UK). One sensor is placed per room at 170 cm (head height) to sense motion within the room and participant transitions from room to room. A straight "Sensor Line" of four restricted-field sensors at 61 cm intervals is placed on the ceiling of a hallway or other area where the participant walks regularly at a consistent pace. This sensor line allows unobtrusive gathering of walking speed many times per day; thousands of walks a year [15-17]. Other metrics can be derived from these activity sensors such as dwell time or number of room transitions [18]. Door sensors are placed around the home at all external doors to detect home entry and exit, and on the refrigerator to determine general frequency of food access.

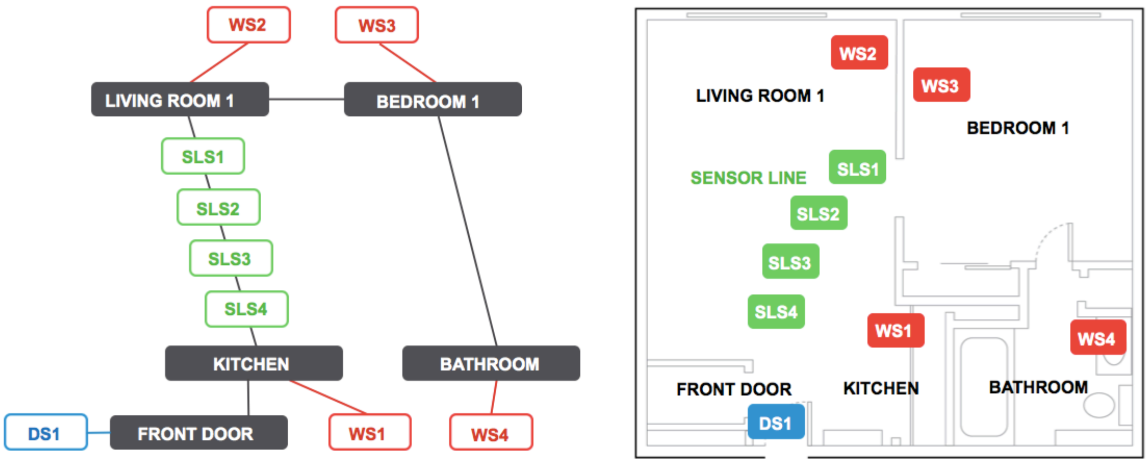

Figure 2. Graphing tool for recording the PAN of a home (left). Each room in a home is linked to the others based on possible room transitions. Sensors are linked to the rooms in which they are located. The sensor line sensors (SLS1-4) in a home consist of four restricted field passive infrared sensors linked together in the order under which a person passes as they walk (in this case from kitchen through living room). Wall mounted sensors (WS) provide room-level location of activity. A front door contact sensor (DS1) is also shown in this network. Corresponding simple home floor plan is shown on the right.

On-line Self-Report System and Computer-based Monitoring: To augment the passive system of collection devices, it is critical to collect self-report and event data in the home to annotate the data streams and provide insight into internal states that can only be self-reported (e.g. feelings of pain, mood) or events external to the sensors (e.g., visit to an ER). To provide this data a brief (on average 4.2 minutes to compete 13 questions) online weekly self-report **Personal Health and Activity Record** (PHAR), is populated that can be completed on any device with an internet connection to query participants about trips out of the home, visitors in the home, health changes (including ER visits, hospitalizations), space changes within the home, need for home assistance, loneliness, depression, and pain level (see **Figure 3**). Weekly data collection requires a relatively short window of recollection, which provides much higher likelihood of accuracy than, for instance, annual surveys. Further, this self-report process also allows for passive indicators of cognitive impairment to be captured [19, 20], such as variation in the time to complete the survey, variation in number of clicks, or increased difficulty reporting accurate dates. In addition to weekly on-line report, we also install computer use software on the participant's computer (WorkTime, RescueTime) that provides data with regard to overall computer use (keystrokes, mouse movements), as well as time in specific applications or web browsing which may be indicators of cognitive or health change [21].

MedTracker: An ORCATECH-developed medication tracking device, the "MedTracker" [22, 23], is installed. This seven-day pillbox records whether or not the designated day's compartment was opened and the time(s) that it was opened each day. Participants using the pillbox provide their daily medication regimen to the research staff updated weekly in the PHAR. This provides valuable information about medication adherence as well as a potential indication of cognitive decline if consistency of medication-taking decreases.

Phone Monitor: A phone monitor (Shenzen Fiho Electronic, Fi3001B) is placed on landlines in homes with landline phones in order to record frequency, time of use and whether calls are incoming or outgoing. This device also allows analysis of variation in phone numbers called. If a participant does not have a landline, cell phone records are used and entered into a phone database for this analysis. These records provide indicators of social engagement or isolation [24] .

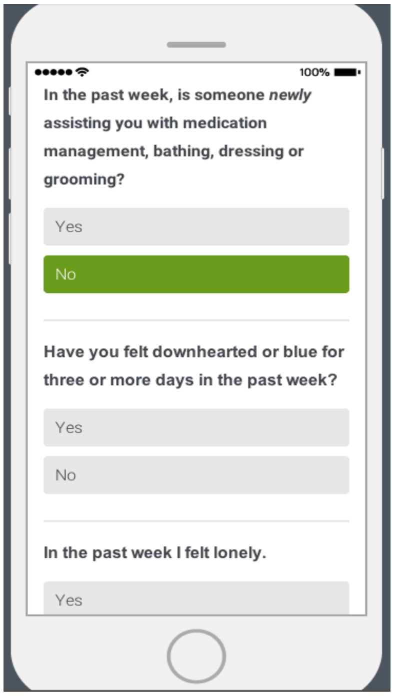

Figure 3: Screen shot showing questions presented for the weekly personal health and activity record (or PHAR) on a mobile device. "Yes" responses result in a drop-down menu that asks for further detail. The survey is tracked for timing of each item response and total time to complete the survey each week.

Physiological Monitoring: A wireless digital bio-impedance scale that also collects pulse, environmental temperature and ambient CO_2 level (WS-50 Smart Body Analyzer, Withings, Cambridge, MA) is installed in the bathroom to collect data on participants BMI and the other indicators. Participants are instructed to stand on the scale each morning. These data may then be correlated with other reported events (e.g., health status), as well as participant heart rate, room temperature, ambient CO_2 level, and other passive indicators of behavior, such as protocol adherence and frequency of use over time.

Additional Possible Components: As CART evolves, researchers may choose to supplement the basic sensor set with additional data-collection components. Examples tested in the past include development and implementation of a digital "Wii" balance-board for balance testing, an iPad with periodic cognitive tasks for the participant to complete in their own home, and an automated texting system to evaluate the efficacy of medication reminders via phone. Importantly, we will deploy two additional technologies for development that are currently available and will provide key functionality for the final DP platform (V2.0). These are further described below (see **Section 3.3 Iteratively, optimize and add needed functionality to the system).**

Deployment in the Community: The components of the system are deployed into a participant's home using the following protocol. Site team deployment training and support are described in the subsequent section **Developing and refining the infrastructure based on the CART V 1.0 design.** Space limitations allow for only a summary of the technical setup here. A draft CART technical users manual is available (see Appendix) and provides additional detail.

Deployment of the CART platform to the sites begins with the **Resource Core** preparing the technology. Before going to any home, all equipment is added to our inventory system and tagged with a QR code assigning the equipment to a home. The home Plug PC that aggregates the data is imaged with our software using the open-source configuration management utility, Puppet [25]. Once all equipment (motion-activity sensors, contact sensors, MedTracker, phone monitor, bioimpedence scale, etc.) for a home is inventoried, imaged and packed into an installation kit, the installation can occur in a home.

In the participant's home, the first action is to set up the Plug PC and secure its internet connection (provided by our CART project as the majority of volunteers will be of low income or modest means). Once the Plug PC is connected to the internet, using Puppet, we ensure the system is using the most current software versions. We then connect an internet enabled device (laptop, tablet, cell phone) to the Plug PC's wireless network to access the local control panel website. Once we access the control panel we then set the Home ID, which allows us to see the status of the Plug PC as well as any sensors installed in the home.

After the Plug PC is set up, other sensors are added to the home. For each device/sensor placed in the home, we scan the QR code which takes us to our website that allows us to assign it to that specific home. We re-run Puppet so that the appropriate software is installed, then configure each type of device required for the home and confirm collection of the expected data from each device.

As sensors are successively added (motion sensors, contact door sensors, etc.), the home PAN (Personal Area Network) is created. This generates in the sensor placement website a plan of the home using a node-edge structure (**Figure 2,** above). For each device care must be taken to ensure that the device is assigned correctly through the online inventory system and that it is configured and oriented to operate properly considering its communication protocol. For example, the MedTracker is Bluetooth enabled and thus needs to be in range of the Plug PC to receive this signal. The scale requires a solid surface, so it is typically installed in the bathroom. For set up, an app is used to configure the scale via Bluetooth using a phone or tablet. The scale is set up to communicate through the Plug PC's wireless network during the setup. Once the scale is set up, the participants stand on the scale to test the device's functions. Computer use software is installed on the participant's computer and their e-mail address is recorded to send the participant's weekly PHAR survey.

Once all the devices have been installed in the home, we confirm that data is being collected properly via the control panel. A post-install check provides confirmation that the Plug-PC can communicate with our main servers to transfer data, that the Home ID is set and the services to collect the data for each device type are running. We view a live graph of motion sensor data while we walk through the home to confirm each sensor is firing. A call is made to and from the home to test the phone monitor. The MedTracker is opened and closed a few times to test the device. We then review the most recent database activity to confirm that each device is saving the data into the database. All information is transferred via secure encrypted internet connections to our OHSU server system at the Advanced Computing Center, designed to handle sensitive health information and related data (the same secure ICT system used by for example the established telemedicine programs).

After successful installation and setup, participants will be instructed to live their lives as they would normally. *The primary focus of the V1.0 deployment will be understanding the unique needs of the use cases, understanding the users (e.g. with interval surveys, user testing and focus groups), refining the metrics and problem solving technology integration and remote deployment.* After describing in the next section further functionality to be developed, analysis of both V1.0 and V2.0 is described below in the section titled, ***CART System Development Life Cycle Assessments.***

3.3 Iteratively, optimize and add needed functionality to the system in subsequent versions of the platform leading to a final "CART 2.0" for the DP.
To construct a system that has maximal functionality for the DP there are several anticipated key modifications and advances that need to be carried forward during the years of the development cycles. Although there are many possible areas to work on we have prioritized several high impact areas. These areas are called out in the white paper from the Trans-NIH/Interagency workshop leading to this FOA [26], the literature [5, 27, 28] and our decade-long experience in this research. We are further guided by practicality, focusing on what can be realistically accomplished with the time, technology, knowledge and resources available. We fully anticipate the Steering Committee and other advisors weighing in on these areas early in the first year and are ready to revise these plans accordingly. The key areas chosen for further needed development leading up to the DP are improving the ability to expand the use cases of the data, advancing out of home capture of data and maximizing the scalability of systems.

Improving the ability to expand the use cases of the data – multi-person home activity discrimination.
Independent, older people spend the vast majority of their time in their home (> 21 hours/day) [7, 29]. Currently, most monitoring of this indoor activity falls into two categories. One either uses passive environment sensing (RFID, PIR, depth sensors) or one uses a wearable (e.g., actigraphy) device. The former case identifies activity at a minimum by room level location, is unobtrusive and requires no interaction by the resident. However, although algorithms or additional sensors can differentiate some cases of multiperson behavior [30], for accurate assessment, the passive approach is currently limited to cases where an individual lives alone. In the case of body worn actigraphy, this approach identifies general activity for the person wearing the device (e.g., steps, walking speed), but when indoors does not identify where the activity occurred and *each* resident needs to wear a device. In addition, these wearable devices require charging and in general have not been designed to be user friendly for older people. Although millions of seniors (one-third of people over 65) live alone, and this demographic is at higher risk for loss of independence than those who live with others, there remains an important need to address the case of co-residents. In particular, the AiP challenge of cases where two older people live alone and one or both partners are frail is especially relevant. A number of technologies are in development that will change this landscape [31, 32]. Bluetooth (BT) low energy beacons, now routinely being deployed in commercial settings to identify a specific person moving near a location of interest (with their

smartphone detecting the BT beacon signal), provide a ready approach for indoor home location research. However, as it is unrealistic to expect seniors to carry smartphones about their homes all the time, the

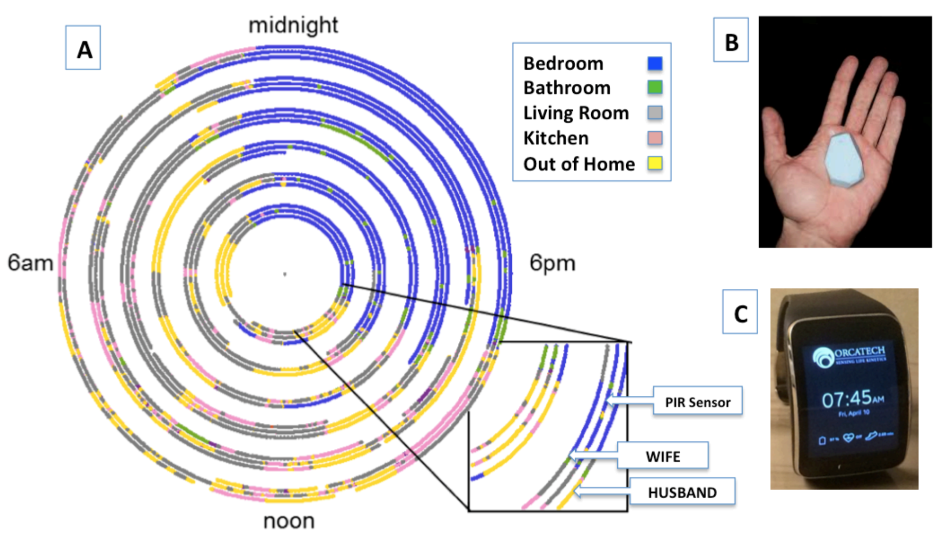

Figure 4. Spiral plot (**A**) depicting the within home location of a husband and wife plotted on a 24 hour clock for 6 consecutive days using a Bluetooth beacon system (**B -** photo of one of the beacons deployed around the home) paired with smartwatches (**C**) for individual localization. Each concentric circle outward depicts one day. In **A,** the colors represent where the person is located (see key). The outer trace is the husband, inner trace is the wife and middle trace is the activity of PIR sensors (see inset).

introduction of an array of *smartwatches* ("smartphones on a wrist") provides a path that can now be used to apply this approach to multi-person location. This wearable solution may provide functionality in addition to location such as frequent vital sign information. However, there are several challenges at this point. These include battery-life, form-factors and user interfaces. We have piloted this beacon/watch solution to better understand the current limitations and feasibility. Based on this preliminary data using a Samsung Gear S and BT beacons sited around the home (see **Figure 4**[33]) we have demonstrated the feasibility of the watch for location sensing in the home. We propose to further develop this approach during the DP development years (see below, ***CART System Development Life Cycle*** section**)**. At first we will rely on this current technology (optimized at time of deployment in V1.0) and then working with our academic and industry partners create a refined version based on the inevitably more user and developer-friendly/usable technologies available at that time for CART research to be deployed in CART V2.0. The focus of evaluation of this system in V1.0 will be basic usability and functionality. In V2.0 deployment, the focus will be on both further tuning of the technology in the field, and in analyzing and creating new metrics such as time spent with a spouse by location (bathroom, bedroom, kitchen, etc.). *With the advent of this functionality, an entire new science of couples or caregiver interaction research will be opened* (see **Figure 5).**

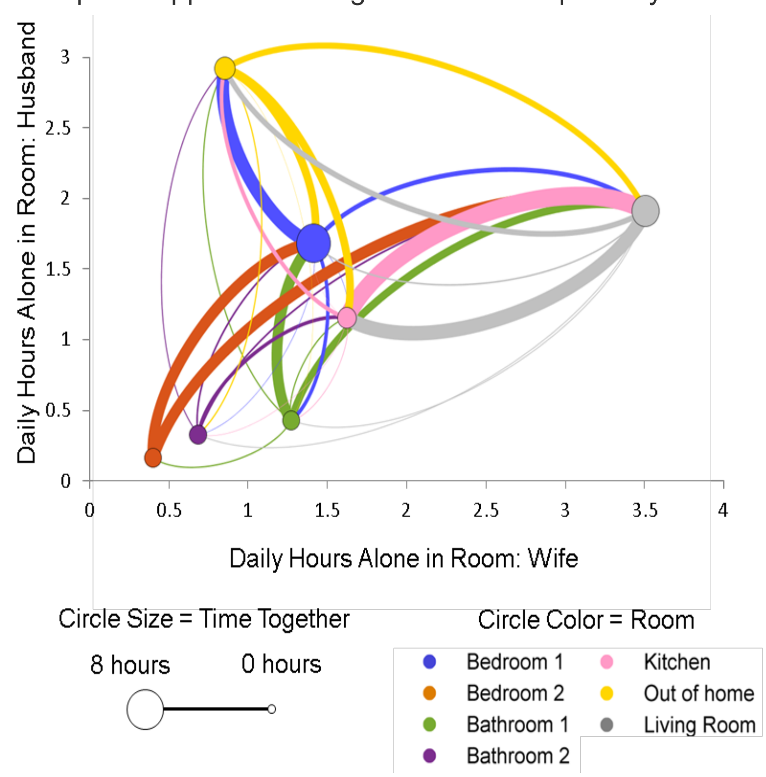

Figure 5. Movement patterns for couple in **Figure 4** living in the same home. Rooms are plotted as a function of the time the two participants spent alone in the room while the size of each room represents total hours spent in the room together. The thickness of the connecting lines represents the transition patterns of the residents: given a resident is in a particular room (e.g. the living room), the thickness of the same colored lines (gray lines) indicate the relative probability of moving from that room to each other room in the house.

***Maximizing the scalability of systems:* "START", Scalability of Technology for Aging Research Tool.**

One of the major challenges to scalability is recognizing that population heterogeneity makes a one-size-fits-all approach counter to successful deployment and subsequent maintenance of the system. Thus each home and its occupants brings unique characteristics that may pose challenges to a general assessment platform ranging from technical issues such as Internet access or unusual home layouts to personal issues such as technology literacy. We have found that approaching a potential senior for participation informed with maximum detail with regard to these priors is critical. However, there is no current tool that covers the prediction of what challenges will emerge prior to installation or what may predict sustained, stable use. Accordingly, we propose to systematically collect information during deployment of V1.0 and V2.0 to guide creation of a general deployment tool with the goal of assisting all those who plan to develop AiP technologies in diverse communities.

Guided by our work [11, 27, 34-36] and others [37-39], the tool will be built with a mixed approach using: 1) surveys of the research teams (including the field teams, the back-end systems staff); 2) surveys of the home occupants and significant others such as family members and care providers; and 3) compiling all instances of experienced technical challenges (e.g., failure to connect to the Internet, sensor malfunctions). Aside from basic user characteristics (age, sex, education, race/ethnicity, etc.), standard and CART-specific survey instruments will be used to identify experiences, attitudes and beliefs about technology and related factors (e.g., cognitive function, self-efficacy) that led to successful deployment and maintenance. These include the Technology Acceptance Questionnaire (CREATE), Acceptance of Technology, a 12-item questionnaire that assessed the usability and utility of PRISM [40]; the ISAAC Technology Survey [41], a 34-item questionnaire organized around relevant topics (frequency and types of computer use, attitudes about unobtrusive monitoring, attitudes about sharing monitoring information with one's family or doctor, concerns about privacy or security); and tailored questionnaires to fit a particular technology (e.g., use of the smartwatch BT beacon location system) [42] or CART protocol elements (e.g., experiences around completing the weekly PHAR) [43, 44]. In parallel, the research teams at the four sites will also be queried with regard to their views of the system. Here the emphasis will be on user experience and deployability. Thus the team will be asked about their experience in working with the system from inception through maintenance. Each of the following domains will be assessed as appropriate: Ease of use; acceptability; reliability; learnability; effectiveness; efficiency; errors; flexibility; memorability; user satisfaction; safety; confidence; aesthetics; convenience; intrusiveness / privacy concerns. Based on these inputs a model will be built that best predicts deployability *and* sustained use. This will be the basis for the CART predictive tool intended to be available for future deployments: the **Scalability of Technology for Aging Research Tool (**or **START)**.

Figure 6. Typical neighborhood walk route of an older person acquired with existing GPS mapping technology used by ORCATECH.

Advancing out of home assessment of independence. As noted, seniors may spend on average 21 hours per day in home. However, the ability to go out and engage in outside activities even for a brief time is a key element of independent living. For some, public transport or age-friendly environments may facilitate AiP, but for many living without nearby services or convenient access to healthcare, leaving home is a challenge. However, little is known longitudinally and objectively about this critical out of home activity. We thus propose to develop: 1) *objective measures of pedestrian activity in neighborhoods* using the A-GPS/GLONASS system (or "GPS") of the smartwatch that our volunteers will wear (used above for in-home person location); and *2) objective driving behavior measures* using commercially available Automatic (automatic.com) on-board telematic devices that connect unobtrusively to a vehicle's On-Board Diagnostic (OBD) port to monitor driving activity. For pedestrian neighborhood activity, the use of the smartwatch's GPS will enable using existing protocols for extracting common metrics of out of home mobility and geographic information system information: distance traveled/time, services accessed (e.g. grocery, clinic, park) (**Figure 6**) [45, 46]. For driving behavior, the Automatic device will be installed in participants' vehicles (compatible with all vehicles sold in the U.S. beginning with 1996 models) and raw trip data will be obtained electronically from each device, processed via cellular link and transmitted to secure servers for upload to our central research database. Raw data available for each trip includes: start location, start time, end location, end time, trip distance, number of hard accelerations, number of hard brakes, and number of seconds over 70mph during the trip (**Figure 7**). A freely available open API allows modification of our software to read the raw trip data and derive the variables of interest. Out of home driving behavior will apply to a subset of participants. Of 114 non-demented participants aged 60-90+ enrolled in existing ORCATECH studies only 15% do not drive at all. Of those residing in section 202 Union Manors housing facilities, 30% drive. Among the MARS cohort in Chicago 69% drove in the last year. Almost all non-demented rural-residing veterans drive. Out of home metrics will be calculated on a daily, weekly and monthly basis including the variability in each measure. Key will be longitudinal analyses where the frequency of data collected allows each participant to serve as their own control and *the change in their usual established pattern provides an overall person-specific measure of their function.* This will allow for examination of within person change. These metrics will be added to the overall model of independence and predictors of successful AiP (see **Figure 1**).

Figure 7. Sample trip data generated from the Automatic telematic device.

Vehicle	Start Locat	Start Time	End Locatio	End Time	Distance (r	Duration (r	Fuel Cost (U	Average MI	Fuel Volu	Hard Accelera	Hard Brake	Dura
2013 Toyota S	4420 Soutl	12/11/15 16:53	16195 SW [	12/11/15 17:17	3.82	23.94	0.6	14.82	0.26	0	0	
2013 Toyota S	3888-4118	12/11/15 16:18	4420 South	12/11/15 16:50	7.32	31.94	0.96	19.05	0.4	0	0	
2013 Toyota S	16195 SW	12/11/15 8:05	3888-4118	12/11/15 8:41	10.22	36.41	1.37	17.88	0.58	0	0	
2013 Toyota S	4150-4216	12/10/15 17:07	16195 SW [	12/10/15 17:29	4.53	21.94	0.68	15.99	0.29	0	0	
2013 Toyota S	16195 SW	12/10/15 6:56	4150-4216	12/10/15 7:13	4.54	17.6	0.66	16.7	0.26	0	0	
2013 Toyota S	22075 Nor	12/9/15 19:22	16195 SW [	12/9/15 19:40	7.64	18.22	0.75	24.7	0.32	0	3	
2013 Toyota S	22075 Nor	12/9/15 18:59	22075 Nort	12/9/15 19:18	6.01	19.17	0.79	18.35	0.32	0	0	
2013 Toyota S	17475 Sou	12/9/15 18:27	22075 Nort	12/9/15 18:51	7.13	23.42	0.84	20.46	0.34	0	1	
2013 Toyota S	16000-161	12/9/15 18:10	17475 Sout	12/9/15 18:24	1.36	14.02	0.44	7.53	0.18	0	0	
2013 Toyota S	16119-161	12/7/15 16:30	16000-161S	12/7/15 16:43	2.88	12.72	0.4	17.41	0.16	0	0	
2013 Toyota S	4650 Soutl	12/7/15 15:38	16119-161S	12/7/15 15:59	3.83	20.98	0.63	14.11	0.26	0	0	
2013 Toyota S	Beaverton	12/7/15 14:25	4650 South	12/7/15 14:36	0.11	11.62	0.01	18.11	0	0	0	
2013 Toyota S	4150-4216	12/7/15 13:29	Beaverton	12/7/15 13:36	2.06	7.5	0.29	17.17	0.13	0	0	
2013 Toyota S	16195 SW	12/7/15 7:37	4150-4216	12/7/15 8:03	4.56	26.44	0.84	13.17	0.34	0	0	
2013 Toyota S	12580 Sou	12/6/15 14:11	16195 SW [	12/6/15 14:24	5.15	13.6	0.58	21.17	0.24	0	1	
2013 Toyota S	16195 SW	12/6/15 12:57	12580 Sout	12/6/15 13:12	5.18	14.82	0.73	16.94	0.32	0	0	
2013 Toyota S	Greenway	12/5/15 20:19	16195 SW [	12/5/15 20:33	5.39	14	0.66	20.23	0.26	0	1	
2013 Toyota S	9405 Soutl	12/5/15 19:32	Greenway	12/5/15 19:38	1.21	5.33	0.19	15.52	0.08	0	0	

CART System Development Life Cycle (SDLC) Assessment**: **Developing and refining the infrastructure based on CART V1.0/V2.0 designs, study requirements, user-testing and iterative system deployments.
Here we review and briefly recapitulate for clarity the iterative development, deployment and assessment extending until the end of year 3 when the DP formally begins. The Core-related aspects of this approach have been discussed in the preceding Core sections. The focus of the first cycle of deployments will be initiated using the basic ORCATECH platform in CART V1.0 to ensure the capacity to assess the major life domains most important for AiP within differing populations. The starting platform was designed with user input and feedback among largely white and African American middle class seniors living in retirement communities. Thus, integral to this activity for each cohort will be assessing usability and modifying as needed among more diverse cohorts. Since most of the system is unobtrusive, save for the weekly questionnaire, the use of the MedTracker pill box (for those that do not use a pillbox), and being asked to stand on the bathroom scale each morning, a particular focus will be usability and acceptability by the participants first living with CART V1.0. For each phase of the SDLC we will use standard scales to assess components, as well as the overall system as described above in the development of the overall **Scalability of Technology for Aging Research Tool** (e.g., Technology Acceptance Questionnaire (CREATE), the ISAAC Technology Survey, and tailored questionnaires). Again, each of the following user-centered aspects of assessment will be addressed as applicable: ease of use; acceptability; reliability; learnability; effectiveness; efficiency; errors; flexibility; memorability; user satisfaction; safety; confidence; aesthetics; convenience; intrusiveness / privacy concerns. In addition (as above), in parallel, the research teams at the four sites will also be a major focus of the assessment of the effectiveness of the system for AiP research queried across the same assessment categories.

For the incremental improvement of the overall system each site will enroll and deploy in first waves of 30 homes. The Portland section 202 housing site team, with long experience in developing AiP technology, will initiate the cascade of development and deployment, followed by the rural VISN20 VA, Chicago and Miami. Prior to deployment an all-sites meeting will be held linked to the anticipated early Steering Committee meeting. Research teams will subsequently be oriented to the technology and provided with hands-on instruction on installation in Portland at the Point of Care Laboratory (a mock apartment for research on campus). Following this instruction, we will mail the CART kit (containing all necessary components needed for installation) directly to the sites. Because this project is in part about understanding best deployment practices we will also send an experienced ORCATECH field technician to the Chicago and Miami sites for initial orientation and local site training as well at the end of the first year. The CART leadership will oversee all activities in order to be responsive to the inevitable introduction of improving technologies. The process of recursive process improvement will be monitored on a quarterly basis over each year according to the 4 major SDLC phases as described in the **Resource Core.**

Assuming the system is acceptable and there are no outstanding issues, the next cycle of development will be initiated to create the final V2.0 to be used in the DP. In this phase, in addition to general incorporation of improvements to overall system and deployment, several major research activities will be conducted including development of: couples' beacon localization system based behavior metrics; out of home assessment (pedestrian and driving activity); and the START. In this phase the already enrolled participants at each site (120 homes; 180 participants) will continue with the new functions added. An additional 30 new homes at each site will be added testing the de novo deployment of the V2.0 system. Thus, by end of year three, 240 CART homes with 360 participants (half living alone) will be consented and ready for the year four DP.

3.4 **Deploy and test the full 2.0 DP System.**
The DP will be conducted over the last year of the proposed CART project. The DP will test the hypothesis that the AiP metrics derived from the technologies employed are capable of measuring and predicting loss of independence or its risk profile. We thus run the DP not only as a longitudinal feasibility study of technology, but operate the DP as a real world study testing a central AiP hypothesis. **The aims of the DP study are to:**

1. Demonstrate 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. The primary outcome measure is the number of transfers to higher (or lower) levels of care. Levels of care will include living independently, assisted living, and skilled nursing.
2. In secondary analyses, determine specific instances predicting transitions: the percentage of days for which medication adherence was less than 80% of desired doses, reduced time and distance traveled from home (adjusted for seasonality and weather using data from our integrated platform) and number of days in which the senior received in-home care for ADL or IADL assistance, the latter by either a professional or informal caregiver. Given that the DP is four years from now, we anticipate that exploring additional or alternative outcomes may be of interest to the Steering Committee and research community at that time; our design is flexible to examining other outcomes of interest.

Participants and enrollment: The DP begins with the already enrolled participants at the four sites. Participants will have consented to the CART research program as a longitudinal study that includes the development phase (years 1-3) and the final DP (year 4). For the CART protocol, subjects will know from the beginning that the focus of the study is to understand how technologies may help people remain independent and inherent to this research process, technologies and procedures will be changing during the study as they are assessed over time. Accommodating these changes, during the development phase periodic amendments will be made to the main protocol based on the results obtained to date. For some new procedures such as asking participants to use a novel device, new specific consent will be needed. We have found that the protocol amendment approach is much more practical and efficient than processing multiple cycles of entirely new protocols through an IRB. To further facilitate this process for this multi-site study we anticipate using a single IRB process consistent with the "Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research"[47]. The VA Portland Health System and OHSU currently have a combined review system that will also facilitate this single IRB process. We intend to include 360 subjects across 240 homes; if prior subjects have left the study before year four, new participants will be enrolled by the sites to meet the baseline DP enrollment goal. We emphasize that we have chosen to continue the cohort already enrolled, rather than enroll entirely new subjects, as a major necessary test is the longitudinal stability and maintenance of the systems (including the 'back-end'). Further, this design allows the important longitudinal tracking of changes in attitudes and beliefs about the technologies over time[40, 48].

Procedures: Baseline in person clinical assessment will include repeating the baseline assessment of the development phase (see above, **3.2 Prepare and deploy CART V1.0, Clinical Data and Assessments).** This will include the ISAAC Technology Survey (ITS), a scale specifically designed and used to assess changes in attitudes and beliefs about technology use including continuous monitoring [40]. The scale includes questions organized around key topics: frequency and types of computer use, attitudes about unobtrusive monitoring and monitoring of computer use, attitudes about sharing monitoring information with one's family or doctor, and concerns about privacy or security. Volunteers rate their level of agreement with statements on a five-point scale (Strongly Agree to Strongly Disagree). We will modify this scale to ask specific questions about the CART deployment (e.g., degree of obtrusiveness of specific components of the platform) and include an open-ended question about suggestions for improvement.

The final V2.0 CART platform will be deployed to all homes. This will involve updating sensors, and ensuring that the latest software and versions of on-line PHAR queries are in place. The participants will be instructed to go about their lives as they normally would. We will capture transitions primarily through the weekly reports. These include recording when additional assistance has been obtained (including formal care such as home health aids, visiting nurses, or 'informal' care such as a relative moving in). Because as a person becomes physically or cognitively impaired they may have difficulty completing the online form, the site team will contact the resident by phone to obtain this information if a participant does not report after an end of week reminder post.

The endpoint for the DP triggering removal of the technology will be when a person physically transitions to a new residence such as assisted living or a nursing home or the project has been completed. An exit interview and assessment using the baseline battery will be given at this point. Although this study is not an intervention, we will provide feedback to the volunteers in the form of weekly views of their data relative to prior weeks. These views will include summaries of things such as total activity, time in bed, time out of home, and weight trends. Because this is a research study, we will not yet be able to tell residents that we know when they are about to fail or transition. However, we will be obligated to report any clinically significant findings that we discover to the volunteer or consented parties. This will be explicitly described in the consent process.

Analysis: The number of potential variables to predict loss of independence (LOI) derived from the full DP system is expected to go well beyond 500 (see data model, **Figure 1**). This is partly because most functions could have multiple indicators such as daily and weekly means, median, variability, minimum and maximum as well as subject-specific thresholds (e.g., see [1]). We will select a set of variables that maximize the ability in predicting LOI using a 'big data' analytical approach (e.g., SVM including random forests and logistic regression models). We will split 360 subjects into 5-fold cross-validation (CV) sets using 4 sets for training and one set for testing and assess the average accuracy, sensitivity, specificity and AUC for the fused set of variables. We will repeat the 5-fold CV procedure and update the overall performance after every iteration and stop the iteration as the performance criteria converge to a steady state. In addition to the data driven approach, we will also select a set of variables on a conceptual basis from categories shown in **Figure 1** for specific hypotheses. Thus, for the secondary outcomes (number of days when participants failed to take medication correctly, reduced out of home activity, use of in-home care assistance), we will use generalized linear mixed effects models with the occurrence (e.g., days with occurrence of set thresholds) of these incidences as outcomes in longitudinal analyses, which we have shown improves statistical power and prediction accuracy [1].

Power: We will follow 360 subjects for up to 12 months using the full DP system in year 4. Historically, 10-29% of residents per year transfer temporarily or permanently to a higher level of care depending on age, health and support. For example, within the ISAAC study population [7], 14% of participants transitioned in 2010, reflecting the healthier status of this volunteer cohort. Given the overall profile of the intended enrollees for CART, we conservatively estimate that 14% will transition per year with 10% drop-out (including mortality) per year. Thus 45 will lose independence during year 4. Given this LOI incidence, we would have over 94% power to detect the difference in AUC by 15% with AUC under the null hypothesis being 70% (i.e., AUC using demographic variables such as age, gender and education is 70%, while AUC using DP metrics is ≥ 85%; α=0.05, two tailed). Preliminary analysis of a Life Lab cohort of 91 relatively health seniors (mean age 83) monitored for a mean of 392 days with a platform providing only motion-activity, computer use and weekly self-report data detected with > 90% accuracy the 10% who transitioned to more advanced care within a year. Therefore, the above scenario is conservative.

The data and findings generated from the DP will be used to refine the operation and gauge statistical power needed for results that can be expected from the operation of the project at larger scale in various settings. At the conclusion of the DP, a report will be completed and several publications submitted describing the results, assessing the study design and sharing insights and knowledge gained for application to the future Phase II scaling efforts.

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Budget Justification: Section 202 Housing Residents, Portland Site (Portland 202)

DEMONSTRATION PROJECT, PORTLAND 202 A. PERSONNEL

Jeffrey Kaye, MD *Portland 202 site PI (0.6 calendar months per year)*
Dr. Kaye, as site PI, will be responsible for oversight of the conduct of the recruitment, enrollment, assessment and retention of the elderly residents residing in section 202 housing in Portland. He will have responsibility for ensuring that participants are enrolled in a timely fashion and that all assessments are performed to standard. He will also be responsible for reviewing the clinical data for accuracy and for oversight on clinical issues as they typically arise in longitudinal studies (e.g., recruitment and retention). This cohort will also be clinically characterized using clinical Life Lab standards (Kaye, 2011), facilitating the addition of detailed cognitive and other clinical measures included in the Uniform Data Set of the National Alzheimer's Coordinating Center (similar to the Rush cohort). These participants' (30 for V1.0 and 30 for V2.0 studies) data and their status in the project will be reviewed by Dr. Kaye with regular weekly meetings with Ms. Duncan and Ms. Ross (see below).

Citation: Kaye JA, Maxwell SA, Mattek N, Hayes TL, Dodge H, Pavel M, Jimison H, Wild K, Boise L, Zitzelberger TA. Intelligent Systems for Assessing Aging Changes: Home-Based, Unobtrusive and Continuous Assessment of Aging. Journal of Gerontology: Psychological Sciences, 66 (Suppl. 1): i180-i190, 2011. PMC3132763

DEMONSTRATION PROJECT, PORTLAND 202 B. OTHER PERSONNEL

Colette Duncan *Clinical Research Assistant (2.4 calendar months in year 2, 1.2 calendar months in year 3)*
Ms. Duncan is a research assistant with 15 years of experience coordinating follow-up of community-based volunteers in aging studies. She will be responsible for recruiting and following volunteers at the Portland section 202 residents site de novo, including screening, consent, as well as baseline and annual standardized clinical testing.

Ariella Ross *Research Assistant and Field Technician (6 calendar months in year 2, 12 calendar months in years 3 and 4)*: Ms. Ross is a field technician with over a year of experience in ORCATECH homes, responsible for configuring, installing and testing technologies deployed into subject homes. For the section 202 residents cohort, she will be responsible for installing in-home assessment platforms and orienting volunteers to the in-home assessment system, including the weekly online health questionnaire. When system issues arise that require an in-person fix, Ms. Ross will schedule with participants and remedy any problems.

DEMONSTRATION PROJECT, PORTLAND 202 C. EQUIPMENT: None

DEMONSTRATION PROJECT, PORTLAND 202 D. TRAVEL:

D.1. Site team travel to volunteer homes: Site team members will travel to volunteer homes to consent, enroll and assess subjects, and to install the in-home assessment platform. We request travel funds for: 15 round-trip miles per home, 2 trips to each home per year, at $0.54/mile reimbursement (adjusted to match federally set rate) for each of 60 homes, adjusted according to anticipated enrollment. We request $410 in year 1; $531 in year 2; $304 in year 3; $122 in year 4.

DEMONSTRATION PROJECT, PORTLAND 202 E. PARTICIPANT /TRAINEE SUPPORT COSTS

E.1. Volunteer stipends: We request funds for volunteer stipends to incentivize their time and effort, as well as to compensate for broadband service required for the study. We request $50 per month of participation per volunteer home ($600/year per home). Calculated based on anticipated enrollment and months of active participant enrollment, we request $6,300 in year 1; $31,500 in year 2; $31,500 in year 3; $36,000 in year 4.

Budget Justification: VA Portland Health Care System (Portland VA)

NOTE: As directed in the FOA, we include here a budget and associated justification for a proposed VA component. This will be formally submitted in a separate process directly to the VA upon notice of CART award.

DEMONSTRATION PROJECT, PORTLAND VA A. PERSONNEL

Deniz Erten-Lyons, MD *Portland VA site PI (0.6 calendar months year 1; 1.2 calendar months in years 2-4)*
Dr. Erten-Lyons is a geriatric neurologist with over a decade of experience at the Veterans Affairs Portland Health Care System diagnosing and treating patients with neurodegenerative dementias, and has unique expertise in the neurological evaluation and cognitive assessment of older individuals. She has extensive experience conducting clinical research in brain aging and dementia using data from the Oregon Alzheimer's Disease Center, and has been involved in research and clinical interventions utilizing technology to improve the quality of care provided to patients with dementia. In particular, she has extensive experience with the use of remote technologies in the form of telemedicine. She is lead neurologist for the VA Portland Health Care System's neurology telemedicine dementia program, conducting visits with rural satellite VA clinics statewide, and plays an active role in the national VA initiative to implement telemedicine in neurology. She also serves as Co-PI for the Alzheimer's Care via Telemedicine for OregoN (ACT-ON) study, a state-funded research study of the feasibility and use of telemedicine technology to improve the quality of care in dementia, with a focus on underserved rural elderly individuals. In line with the CART program, this unique research effort brings telemedicine directly into participant homes. Dr. Erten-Lyons is highly qualified and eager to collaborate with Dr. Kaye and Mr. Agritelley on this important project and lead the VA rural-residing veterans research site of CART that aims to use technology to improve health and quality of life for aging veterans and civilians.

Dr. Erten-Lyons as site PI will be responsible for oversight of the conduct of the recruitment, enrollment, assessment and retention of the participants recruited from the VA Portland Health Care System residing in rural areas of the Pacific Northwest. She will have responsibility for ensuring that participants are enrolled in a timely fashion and that all assessments are performed to standard. She will also be responsible for reviewing the clinical data for accuracy and for oversight on clinical issues as they typically arise in longitudinal studies (e.g., recruitment and retention). This cohort will also be provided the extensive clinical characterization with standard clinical and biomarker measures of the Life Lab (Kaye, 2011) through the Roybal Center (at no additional cost to CART) facilitating the addition of detailed cognitive and other clinical measures included in the Uniform Data Set of the National Alzheimer's Coordinating Center. These participants' (30 for V1.0 and 30 for V2.0 studies) data and their status in the project will be reviewed by Dr. Erten with regular weekly meetings with Ms. Duncan and Ms. Ross (see below).

Citation: Kaye JA, Maxwell SA, Mattek N, Hayes TL, Dodge H, Pavel M, Jimison H, Wild K, Boise L, Zitzelberger TA. Intelligent Systems for Assessing Aging Changes: Home-Based, Unobtrusive and Continuous Assessment of Aging. Journal of Gerontology: Psychological Sciences, 66 (Suppl. 1): i180-i190, 2011. PMC3132763

DEMONSTRATION PROJECT, PORTLAND VA B. OTHER PERSONNEL

TBD *Clinical Research Assistant (6 calendar months in year 1; 9.6 calendar months in years 3-5)*
This Clinical Research Assistant will be responsible for recruiting and following volunteers at the Portland VA site de novo, including screening, consent, and baseline and annual standardized clinical testing as summarized in the Demonstration Project section.

TBD *Research Assistant and Field Technician (6 calendar months in year 1; 9 calendar months in year 2; 8.4 calendar months in year 3; and 6 calendar months in year 4)*: This Field Technician will be responsible for installing in-home assessment platforms and orienting volunteers to the in-home assessment system, including the weekly online health questionnaire. When system issues arise that require an in-person fix, they will schedule with participants and remedy any problems.

DEMONSTRATION PROJECT, PORTLAND VA C. EQUIPMENT: None

DEMONSTRATION PROJECT, PORTLAND VA D. TRAVEL:

D.1. Site team travel to volunteer homes: Site team members will travel to volunteer homes to consent, enroll, and assess subjects, and to install the in-home assessment platform. Since the Portland VA cohort will be rural-residing, we anticipate increased travel costs for staff as they complete study visits. We request travel funds for: 52 round-trip miles per home, 2 trips to each home per year, at $0.54/mile reimbursement (adjusted to match federally set rate) for each of 60 homes, adjusted according to anticipated enrollment. We request $949 in year 1; $1,792 in year 2; $1,474 in year 3; $421 in year 4. In addition, we request lodging in the amounts of $3,042 in year 1; $5,742 in year 2; $4,725 in year 3 and $1,350 in year 4. Total travel: $3,991 in year 1; $7,534 in year 2; $6,199 in year 3; and $1,771 in year 4.

DEMONSTRATION PROJECT, PORTLAND VA E. PARTICIPANT /TRAINEE SUPPORT COSTS

E.1. Volunteer stipends: We request funds for volunteer stipends to incentivize their time and effort, as well as to compensate for broadband service required for the study. We request $50 per month of participation per volunteer home ($600/year per home). Calculated based on anticipated enrollment and months of active participant enrollment, we request $2,850 in year 1; $25,425 in year 2; $31,500 in year 3; $36,000 in years 3 and 4.

DEMONSTRATION PROJECT, PORTLAND VA F. OTHER DIRECT COSTS

F.1. Materials and Supplies

CART Platforms will include the following (or similar): Figure from the Resource Core is reproduced here for reference in terms of the sensors and technologies to be supplied.

A basic platform of sensing technology forms the backbone of the overall system for capturing continuous unobtrusive home-based data. Here we describe elements of the platform (as described in the Resource Core and Demonstration Project; See also **Figure** below) and include a table detailing specific component costs. Platform costs listed in the table below represent the costs over the full four years of the project.

Indoor Activity Monitoring

Plug PC and Ethernet Connection Data Hub: A Plug PC (a monitorless CPU; Dreamplug, Globalscale, Anaheim, CA) and Ethernet connection allow data collection from system devices and transmission back to our secure servers at OHSU without participant interference. The Plug PC is configured to the specific participant and home set-up upon system installation using a laptop and our centralized digital participant management system. Additional data collection devices (such as sensors, phone monitor, MedTracker and scale) are configured by communicating with the Plug PC in this way as well.

IR Motion Sensors and Zigbee USB Dongle: NYCE (NCZ-3041, NCZ-3011, NCZ-3045 NYCE, Vancouver, BC) Sensors are digitally assigned to a given home during system installation, communicating with the Plug PC via a wireless Zigbee USB Dongle (ETRX3USB, Telegesis, Buckinghamshire, UK). One sensor is placed per room at 170 cm (head height) to sense motion within the room and participant transitions from room to room. A straight “Sensor Line” of four sensors at 61 cm intervals is placed on the ceiling of a hallway or other area where the participant walks regularly at a consistent pace. This sensor line allows unobtrusive gathering of walking speed many times per day, collecting thousands of walks a year. Other metrics can be derived from these activity sensors such as dwell time or number of room transitions. Door sensors are placed around the home at all external doors to detect participant coming and going from the home, and on the refrigerator to determine general frequency of food access. Typically, 3 contact door sensors and 15 motion sensors are required per home, along with 3M adhesive to install. In addition to the IR motion sensors, Bluetooth Beacons (Estimote) are also deployed strategically about each home and configured similarly to the IR sensors. Participants will be given a Samsung Gear 2S “smartwatch” custom configured for the project to wear all day. Depending on battery life available at the time of project deployment (this is a rapidly evolving area) each participant may be given two watches, one to wear and one to charge so that the participant is always wearing a charged watch and develops a reliable routine (i.e., always wear the watch). In homes with couples this means that each couple in a household will require four watches (two for each resident).

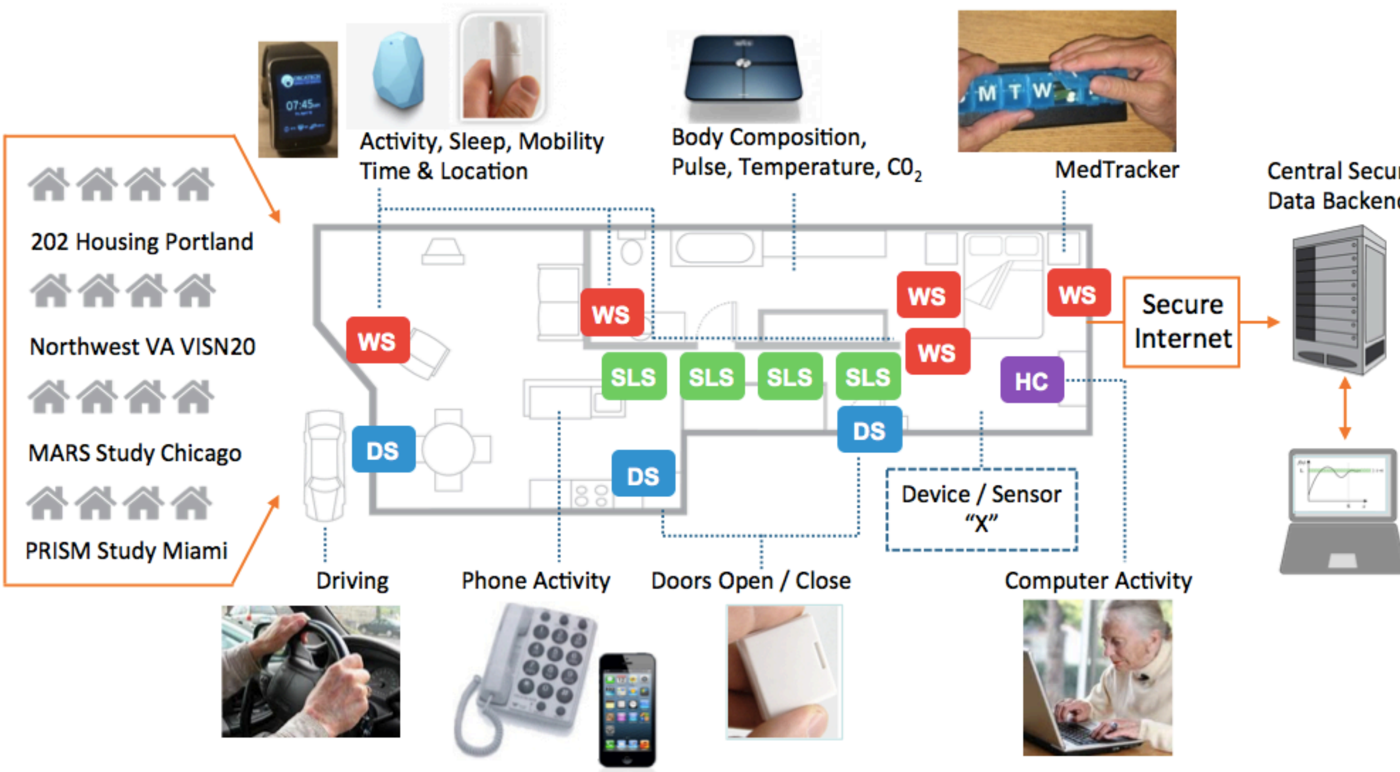

Figure. Schematic of home and community based sensing and reporting platform for CART. The Bluetooth Beacon location system and driving activity sensor (installed in driving residents' cars) are part of development in years 2-3 for the **Demonstration Project** in year 4. **Key:** WS = Wall mounted sensor; SLS = sensor line sensor (ceiling mounted); DS = door contact sensor; HC = home computer.

Outdoor Activity Monitoring: The watch used above will also be GPS enabled and allow for pedestrian tracking outside of the home as described in the Demonstration Project section. In addition, those participants who drive will be invited to consent to having a telematic device (commercial brand: Automatic) installed on the data port of their automobile to facilitate monitoring of driving behavior. We anticipate that approximately 58% of homes will have a driver and car.

Medication Adherence: MedTracker: As part of the basic platform, an ORCATECH-developed medication tracking device (the "MedTracker") is installed that is a seven day pill box that records whether or not the designated day's compartment was opened and the time(s) that it was opened each day. Participants using the pillbox provide their daily medication regimen to the research staff. This provides valuable information about medication adherence as well as a potential indication of cognitive decline if consistency of medication-taking decreases.

Socialization: Phone Monitor: A phone monitor is placed on landlines in homes with landline phones in order to record call frequency, time of use and whether calls are incoming or outgoing. This device also allows analysis of variation in phone numbers called. If a participant does not have a landline (or has both a landline and a cell phone), cell records are used and entered into a phone database for this analysis. These records provide indicators of social engagement or isolation.

Physiological Monitoring: A wireless digital bioimpedence scale that collects in addition to BMI, pulse, environmental temperature and ambient CO_2 level (WS-50 Smart Body Analyzer, Withings, Cambridge, MA) is installed in the bathroom to collect data on participants BMI and other indicators. Participants are instructed to stand on the scale each morning. This data may then be correlated with other reported events (e.g., health status), as well as participant heart rate, room temperature, ambient CO_2 level, and other passive indicators of behavior, such as protocol adherence and frequency of use over time.

TBD 2.0 Upgrade Components: We anticipate that there will be new or additional capabilities that are desired to be included in this project within the next 2-3 years. This may be new functionality to existing devices or novel and more effective ways of collecting similar or new data. Thus we have budgeted for this likely scenario as part of our overall equipment needs. These are included in Platform 2.0 costs below, as well as $40,000 in year 3.

Table: Platform Costs

PLATFORM 1.0			
Item	**#/home**	**$/unit**	**Total**
Hub			
DreamPlug	1	$179.99	$179.99
In Home Activity Monitoring			
NYCE Door	3	$40.00	$120.00
NYCE Motion	15	$50.00	$750.00
3M sticky	5	$4.39	$21.95
Telegesis Dongles	2	$45.00	$90.00
Dongle Plug	4	$3.00	$12.00
CR2 Batteries	36	$1.25	$45.00
Samsung Gear S	4	$329.00	$1,316.00
Beacons	15	$30.00	$450.00
Medication Adherence			
Medtracker	1	$500.00	$500.00
9V Batteries	4	$0.91	$3.64
Socialization			
Phone Monitor	1	$100.00	$100.00
Physiologic Monitors			
Scale	1	$149.95	$149.95
AAA Batteries	20	$0.36	$7.10
		Subtotal 1.0 Platform Per Home	$3,745.63
		Replacement %	10%
		Total 1.0 Platform Per Home	**$4,120.19**
		N Homes; 3 sites	60
		Total 1.0 Platform All Homes	**$247,212**

PLATFORM 2.0 UPGRADE			
Item	**#/home**	**$/unit**	**Total**
Upgrade			
Upgrade TBD	1	$538.00	$538.00
Automatic Car Tracker (58% homes with driver)	1	$50.00	$50.00
		Subtotal 2.0 Upgrade Per Home	$588
		Replacement %	10%
		Total 2.0 Upgrade Per Home Total	**$646.80**
		N Homes; 3 sites	60
		Total 2.0 Upgrade All Homes	**$38,808**

TOTAL PLATFORM COSTS	
N Homes; 3 sites	**180**
TOTAL PLATFORM COSTS; 3 sites	**$286,020**

Program Director/Principal Investigator (Last, First, Middle): Erten-Lyons, Deniz

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 09/01/2016	THROUGH 08/31/2017

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Deniz Erten-Lyons (VA)	PD/PI	0.60			185,100	9,255	2,765	12,020
TBD, Research	Coordinator	6			55,000	27,500	12,121	39,621
TBD, Research	Technician	6			45,000	22,500	10,928	33,428
SUBTOTALS →						59,255	25,814	85,069

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)* CART Platforms	156,236
TRAVEL Subject Home visits and lodging	3,985
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* Research Participant stipends	2,813
CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	**$** 248,103
CONSORTIUM/CONTRACTUAL COSTS — FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	**$** 248,103

Program Director/Principal Investigator (Last, First, Middle): Erten-Lyons, Deniz

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: *Salary and fringe benefits. Applicant organization only.*	85,069	140,464	139,928	128,499	
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES	156,236	66,266	63,566	0	
TRAVEL	3,985	7,528	6,199	1,771	
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES	2,813	25,313	36,000	36,000	
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS *(Sum = Item 8a, Face Page)*	248,103	239,571	245,693	166,270	
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	248,103	239,571	245,693	166,270	
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					$ 899,637

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.