**Protocol**
**PRISM 2.0 in Diverse Living Contexts- NCT03116399**
**August 3, 2018**

## 1) Protocol Title

PRISM 2.0

## 2) Objectives*

This study is part of the CREATE center. The same study will be conducted at Florida State University and Georgia Institute of Technology. Each institution will obtain their own IRB approval for the study. No subjects are being recruited from Weill Cornell Medicine.

The focus of the study is to evaluate the expanded version of PRISM 1.0 for a broad array of seniors with different needs and circumstances. The aims of the study are to: 1) obtain information on perceptions of the usefulness and usability of PRISM 2.0 and interface design issues; 2) examine the impact of access to PRISM 2.0 on social connectivity, engagement, social support, and perceived loneliness; 3) examine the impact of access to PRISM 2.0 on perceived isolation, wellbeing, and quality of life; 4) examine the impact of access PRISM 2.0 on computer attitudes, self-efficacy, technology proficiency and technology uptake; 5) gather data on usefulness of system features and if these vary by living condition; and 6) examine, in our statistical models, the influence of factors such as age, cognitive abilities, ethnicity, education on system use and outcomes.

The study will have 3 phases. We will enroll participants of 65+ yrs in all the phases. Phase 1 (User Testing Phase) will involve general pilot testing of the common core battery (Part A) (e.g., sequencing, instruction, clarity of questions, etc.) and the interface design of PRISM 2.0 in tablet (Part B) (e.g., labeling of icons, content for the features in PRISM 2.0, color, etc.).

Phase 2 (Training script testing phase) will involve pilot testing the training scripts for PRISM 2.0 and for Tablet. The goal is to make sure participants understand the training script and are able to follow the instructions and perform basic activities such as email, internet browsing, etc.

Phase 3 (Trial phase) will be the actual study. It involves randomly assigned eligible participants into the Tablet condition or the PRISM 2.0 system condition. The overall goal of the project is to examine the extent to which the PRISM 2.0 system can help older adults in reducing their social isolation, increasing their social support and social network, and improving their overall well-being and quality of life.

## 3) Background*

We are currently in the midst of multiple converging trends: increased number of older people in the population especially the “oldest old”; rapid pace of technological change and deployment of technology; growing and unsustainable costs of caring for older adults; shift in the medical model towards health self-management and migration of healthcare to the home; decreased number of people available to provide care for the elderly; increased interest in the use of technology to meet healthcare challenges; and the challenges associated with an aging population. Persons 65+ will represent 21% of the population by 2040 and those 85+ are expected to number about 14 million. The diversity of the older population is also increasing and by 2030, minority populations will represent 28% of older adults (Administration on Aging, 2012).

The increased survival and longevity of older adults is one of the great accomplishments of the last century. It also presents challenges for our healthcare system, the economy, and social support systems. Technology is being looked at as a potential solution for these challenges. For example, technology is

quickly becoming a prominent feature of our healthcare landscape. There is a plethora of tools and resources available on the Internet that could help older adults engage in health management tasks. These include websites with information about health resources, treatment options, and tools for health promotion. Further, many health services and benefit programs are increasingly available solely in "online formats." Advances in telemedicine and assistive robotics are also abounding.
Technology holds great potential for improving the quality of life for older people. For example, the Internet can provide access to information and services and facilitate the performance of daily tasks. The Internet can facilitate access to community resources, which may be particularly beneficial for older people with mobility restrictions, especially elderly living in rural locations who often confront problems with geographic isolation (e.g., Rosenthal & Fox, 2000). Learning about the availability of services, such as cleaning, and home repair services may also help older people. Even seniors who are not socially isolated have unmet needs such as getting help with daily tasks, accessing resources, housing repairs and doing routine errands. The Internet can be used to expand educational and recreational opportunities (e.g. Czaja & Lee, 2012). In fact, e-learning is becoming one of the most popular forms of training within industry and education industry (Willis, 2004). Research (e.g., Baltes & Smith, 1999) clearly shows that cognitive engagement is important to successful aging. The Internet and other technologies can also facilitate communication between older adults and family members and friends, especially those who are distant. Social isolation is associated with poorer quality of life and life satisfaction; poorer mental and physical health status; cognitive deterioration and increased mortality (Cantor & Sanderson, 1999; Dykstra, 1995; Ellaway, Wood, & MacIntrye, 1999; Ellis & Hickie, 2001; Fagtiglioni et al., 2000; Aylaz et al., 2012; Shankar et al., 2013; Steptoe et al., 2013). This is a particular problem for older adults who live alone, which is a large percentage of older adults, especially older women in the older age cohorts (Federal Interagency Forum on Aging-Related Statistics, 2012). Older adults in assisted living facilities (ALFs) are also confronted with loss of social connections and physical separation from familiar places and routines, which contributes to diminished mental and physical health (e.g., Ball et al., 2000). Older adults in senior housing units may also face problems with isolation. Housing units, especially for underserved elderly, may be far removed from family members or from neighborhoods in which they have lived and built social networks.

However, advances in technology do not necessarily imply successful and meaningful diffusion of these systems. Judgments of impact, significance, and meaningfulness of applications of technology must be subject to the same evaluation criteria used to evaluate other interventions including: study design, sample size and composition, statistical power and analytic methods, and the reliability and validity of measures (Awan, Wiley & Nobel, 2007; Schulz et al, 2003; Vimarlund & Olve, 2005). Recent research has begun to quantify the value of technology for older adults and issues associated with barriers to access. Although the findings are mixed (e.g., Slegers et al., 2008), overall, the results of these studies are encouraging in terms of demonstrating the value of technology for older adults (e.g., Czaja et al., 2013; Cotten et al., 2013; Woodward et al., 2010).

Our plan is to evaluate an expanded version of PRISM (PRISM 2.0) with older adults in diverse contexts. The design of the PRISM 2.0 is well grounded and the chosen features will be based on: 1) the findings from the PRISM 1.0 trial; 2) the cognitive, human factors engineering and HCI literatures; 3) emerging findings in aging (e.g., findings related to technology acceptance, social isolation, social networks, life engagement); 4) existing theories of aging (e.g., Stress-Process Model, Pearlin et al., 1990; Active Theory, Rowe and Kahn, 1998; Social Isolation/Engagement, see Victor, Scrambler, Bond, & Bowling (2000) for review; 5) findings regarding the benefits of technology for seniors (e.g., Czaja et al., 2013; Cotten et al., 2013; Woodward et al., 2010; 6) findings from previous work from CREATE regarding interface design, training, provision of environmental support, and the needs of older adults

(e.g., Czaja and Sharit, 2012, Fisk et al., 2009; Mitzner et. al., 2008; 2013; Rogers and Morrow, 2008); 7) recent findings regarding Internet use among older adults (e.g., Zickuhr & Smith, 2012); 8) findings from our prior focus groups on barriers to access of technology and technology preferences (e.g., Mitzner et. al., 2008); 9) findings from our technology-based community intervention programs with older adults (e.g., Czaja et al., 2013); 10) existing models of technology adoption and diffusion (e.g., UTAUT, Venkatesh, 2003, TAM, Bagozzi, 2007; Geroski, 2000); 11) the literature on implementation science (e.g., Curran, Mukherjee, Allee, and Owen, 2008); and 12) our planned focus groups and pilot testing of PRISM 2.0.

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## 4) Inclusion and Exclusion Criteria*

The study involves 3 phases. We will begin with Phase 1 of the study and we will provide more information about Phases 2 and 3 as we get ready to embark on it.

Phase 1 & 2 User Testing Phase and Training Script Testing Phase: eligibility criteria:

- Age 65 years of age and older
- Speak English

Phase 3 Trial Phase: inclusion criteria

- Age 65+ years and older
- Speak English or Spanish
- Residents of assisted living facility or independent housing in community
- Not working for a pay or volunteering for more than 5 hrs/week
- Minimum usage of computer/tablet/email/internet in the past 3 months
- Minimum attendance of senior center or participation in social activities
- Passing score of Telephone Interview for Cognitive Status (TICS) at least 24
- Passing score in social isolation ≥ 6
- Passing score in the Brief Technology Proficiency Screening ≤ 14
- Vision at least 20/70
- Woodcock Johnson Passage Comprehension (English at least 33; Spanish at least 34)
- Fuld Object Memory Evaluation (aged < 80 at least 19; aged ≥ 80 at least 18)
- *Memory Impairment Screening* – this will only be administer to those participants who score up to 2 points below the current Fuld cut-off score. Passing score ≥ 5.

## 5) Procedures Involved*

**Phase 1: User Testing Phase**

This phase of the study will have 2 parts and all the activities will be one-on-one with one of our CITI certified Research Associate (RA). Each part will last between 2- 3 hours and breaks will be provided. Each part will have about 10 participants. Participants might be able to participate in both parts. However, they might be required to come to our office for 2 times – one time per part. There might be other RAs observing the activities of these parts. They will be silent observer and making notes of the activities.

We will contact those older adults who have given us the permission to be re-contacted for future technology-based study (e.g., eProst #2010-0482). One of our CITI certified RA will contact and ask them whether they will be interested in being part of the study. Those who agree to participate will be given an appointment.

During the date of the appointment, the RA will present the Informed Consent Form and read it to/with the participant. We are requesting waiver of signed consent form for this phase because this will be the only document linking the participant to their participation of the study.

Participants in Part A of this phase will be provided with the Assessment Battery booklets which has a) socio-demographic questions; b) experience with computer and technology, and technology proficiency and readiness; c) perceptions of health, social support, and memory functioning; d) cognitive tests (e.g., MoCA, Trials A & B, WAIS Vocabulary, New Vital sign, etc). While participant is completing the questionnaire, a RA will be timing and making notes of issues during the administration (e.g., difficulties, clarifications, understanding). The sequence of administration of questionnaires might vary at the discretion of the RA or upon the request of the participant.

Participants in Part B will be completing a user testing of the PRISM 2.0 system. We have created and attached a guided script. The sequence of talking points might vary at the discretion of the RA and upon the request of the participant. Furthermore, participants are encourage to ask questions. Therefore, we will be limited to the questions presented in the guided script. The RA will begin by introducing and demonstrating the PRISM 2.0 to the participant. Participants will be given an opportunity to explore PRISM 2.0 by themselves. The RA will provide some basic cueing questions (e.g., let's try another feature, let's open an email, how about trying to access this app, let's find out what is happening in Miami Beach, etc.) to make sure the participants go through all the features. Another RA will be present to take notes of any issue from this demonstration.

**Phase 2: Training Script Testing Phase**

We will use the same procedure as Phase 1 to reach out to potential participants. This phase will include 3 one-on-one sessions with our CITI certified RA. Each of the sessions will last about 90 minutes. The RA will work with the participant in selecting the best dates and times for these training sessions.

During the date of the appointment, the RA will present the Informed Consent Form and read it to/with the participant. We are requesting waiver of signed consent form for this phase because this will be the only document linking the participant to their participation of the study.

Participants will be provided a booklet of questionnaires which has a) socio-demographic questions; b) experience with computer and technology; and c) proficiency with mobile devices. Upon the completion of the questionnaire, the RA will begin with the script that has been developed to demonstrate the PRISM 2.0 system OR the regular tablet.

The training on using PRISM 2.0 system OR the tablet will continue on Day 2 and Day 3. At the end of Day 3, participants will complete a brief questionnaire about their likes and dislikes of the PRISM 2.0 OR tablet. At the same time, the participant will have the opportunity to express verbally about their perception of the training script and the extent of the usefulness of the training.

Another RA may or may not be present to take notes of any issues during these training sessions. The sessions will be audio recorded to facilitate the review of the successfulness of the training script testing.

**Phase 3: Trial Phase**

This phase of the study will be conducted in English and Spanish depending on the language of preference by the participant.

We will enroll participants who meet the inclusion criteria stated in above section. We will screen about 950 participants and enroll about 300 participants. Participants are capable to provide consent for their participation. All the RAs are CITI certified.

The study has a duration of 12 months and involves a brief telephone pre-screening, 3 home-based assessment visits (baseline, 6 months and 9 months), 3 home-based training sessions, 3 telephone check-in calls (10 days post 1st home training session, 3 months, and 7 months), and 1 brief telephone follow-up (12 months). The study will be conducted in English and Spanish. We will obtain the approval of the English material first, then submit a forward and backward translation in order to seek the approval of the Spanish material.

Eligible participants will receive a tablet with internet connection until month 9th (after the follow-up). They will be working one-on-one with a RA throughout the study. They will randomly assigned to the Tablet Condition or the PRISM 2.0 system condition. Those in the PRISM 2.0 system condition will have their tablet pre-loaded with an app that we developed. This is the app that we have been evaluating and testing in previous phases. Those in the Tablet condition will have a brand new tablet with the native apps that are in the tablet. Participants will receive $30 for completing each assessment and $20 for completing the telephone follow-up. They will receive a total of $110 of financial compensation. Participants will also be able to keep the tablet at the end of the study if they choose to.

As part of the study, we will be collecting participant usage data in the tablet. The data collection will include counts of different activities in the tablet. For example, how many times they visited the Learning feature? How many times they Skyped with family members? How many times they accessed Social media sites (e.g., FaceBook, Instagram, etc)? We will not collect any identifying information.

*Recruitment/Pre-screening:*

Upon the approval of the study promotional material, we will display and distribute material in the Assisted Living Facilities (ALFs) and independent living facilities, and community. In order to get the support from the facilities, we will be visiting them and present the study to the stakeholders of the facilities.

Interested participants will contact study-team via telephone or email in order to obtain additional information about the study and check on their eligibility status. The eligibility status is determined via a brief telephone pre-screening of about 20 minutes. During the phone call, the RA will begin by explaining the purpose of the study, follow by procedure, risk and benefits. The RA will obtain a verbal consent from the potential participant prior to proceed with a series of questions to assess and determine their eligibility criteria (see the telephone pre-screening script and telephone pre-screening form). We are requesting the waiver of signing of Informed Consent Form (ICF) for the pre-screening. At this point, it is not feasible nor possible to obtain a written consent from the participant because this step takes place over the phone. Having to have a written ICF for this step will mean an in-person pre-screening which will be costly and not efficient because some of these participants might not be eligible. We will obtain a written and signed ICF during the first visit at the participant's home.

*Baseline assessment visit (home visit):*

When participant is determined as eligibility to participate, the RA will schedule a visit to the participant's home. This first home visit could be as long as 2.5 hours depending on the participant. Upon the arrival of the RA at the participant's home, the RA is to begin by introducing the ICF to the participant. The RA will read and review the ICF with the participant and make sure he/she understands it before signing the form. The ICF will include permission for audio/video recording for research or education/training purpose. None of the study-related activities can begin until the participant signs the ICF. The RA will provide a signed and dated ICF to the participant for his/her records.

The first study-related activity is further determine whether the participant is eligible for the study. The RA will administer the vision test, the reading comprehension test (i.e., Woodcock Johnson), and the brief memory test (i.e., Fuld) – there is no particular order to administer these tests. If the participant is not eligible to participate because of any of the above mentioned tests, the RA will administer a brief demographic questionnaire so we can capture the demographics of those who are not eligible for the study. These non-eligible participants will receive $20 for their time and effort.

Eligible participants will continue with rest of the assessment – see Part 2 Assessment booklet. We will split this part of the assessment in multiple visits if necessary or if the participant makes the request. The sequence of administering these tests might vary and it can be altered at the discretion of the RA and/or upon the request of the participant. The assessment consists of perceptual questions about participant's social support, social network, physical and emotional well-being, and quality of life. Other questions are related to participant's ability to remember words and understand written sentences, and follow instructions. The assessment is multimodal - paper and pencil, verbal, interactive using a computer-tablet. Some instructional words will be adapted accordingly when tests are administered on a computer-tablet instead of in paper and pencil. For example, instead of circle/mark the correct answer, it might read select/choose the best answer. The RA will paraphrase the instruction statements accordingly so the participant understands it. For the quality assurance and adherence to protocol, the assessment will be audio recorded. No recording will be done if participant refuses to give consent for the recording. Breaks will be provided as needed.

Participants will be provided a booklet of assessment – see Part 1 Assessment booklet – for them to complete it before the next visit. This booklet has socio-demographic questions, technology and internet experience, proficiency with computers, etc. The RA will collect and review the answers in the next home visit.

The first home visit will end by asking the participant to enter or open a gmail account in the tablet that they will be using as part of the study. All eligible participants will receive a tablet with internet connection for the duration of the study.

*Training sessions (3 home-based training sessions):*

Eligible participants regardless of their randomization condition (Tablet or PRISM 2.0 system) will receive 3 home-based training sessions to learn to use the tablet and the PRISM 2.0 system. Each of the training sessions will last between 60 – 90 minutes. Breaks will be provided accordingly. These sessions are interactive and involves a lot of practice (see the training scripts attached in eProst). The training scripts are NOT intended to be followed verbatim. These are

guiding points for the RA to follow. Depending on the skills of the participant, the RA will have to provide more detail or more practice exercises as part of the training. The sequence of the training topics might varied at the discretion of the RA and the participant. More training sessions might be provided upon the participant's request.

Participants might receive more than the scheduled 3 home-based training sessions. It depends on the skills and ability of the participant to use the tablet.

*Check-in calls (3 calls):*

The RA will be calling the participant 3 times. These check-in calls are intended to last about 10 minutes. The purpose of the calls are to check-in with the participant to see if there has been any changes in their lives (e.g., moving, grandchildren, illness, vacation, etc.). Participants who need more help in using the tablet might get more check-in calls from the RA.

*Follow-up Assessment ($6^{th}$ and $9^{th}$ months):*

These assessments will be conducted by an RA who is blinded to the randomization condition of the participant. It will have 3 parts: mail, phone, and in-person. The follow-up assessments have all the measures administered during baseline plus PRISM/Tablet Opinion Questionnaire, System Usability Scale, PRISM/Tablet System Evaluation Questionnaire, and a brief interview. We have included these add-ons and Opinion Interview. The administration sequence of these questionnaires can vary upon the request of the participant.

*Telephone Follow-up ($12^{th}$ month):*

This will administered 3 months post the last follow-up. This interview will be gathering whether the participant has continued using the tablet and the extent of their effort in maintaining their proficiency in the tablet and level of loneliness.

## 6) **Data and Specimen Banking***

The study does not collect specimens.

All the data will be stored and secured using the procedure implemented by the Data Manager of Center on Aging. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

Study data request goes through a web-based check-in and check-out procedure implemented by the Center on Aging. The Data Manager of the Center or designee monitors the logs. Upon de granting of the approval, the requester will either get the hard copy of the data or link to access the electronic data. All the data will not contain any identifying information.

## 7) **Data Management***

Phase 1 and 2:

These are piloting testing phases of PRISM 2.0. (i.e., user testing and training script testing). All the information collected will give us feedback to refine the instructions on the questions, to improve the design of PRISM 2.0., and to improve our training script of PRISM 2.0 OR tablet. We are not planning

to do any statistical analysis of the data gathered in this Phase. We will report the basic demographic information (e.g., age, gender, ethnicity, education) of participants in this phase.

Phase 3:

This phase involved randomly assigning participants to the Tablet condition or PRISM 2.0 system condition. There will be 3 data points for each participant. The design is a 3 (Residence Type) x 2 (Intervention) x 3 (Three Measurement Points) between-within groups design with two between subjects factors and one within subjects factor. The between subjects factor is Residence Type (Rural, Senior Housing, Assisted Living Facility [ALF]/Independent housing) and Intervention (PRISM vs Tablet Only). We will use confirmatory factor analysis to test for the existence of two latent constructs: social support/connectivity and loneliness. We will also use confirmatory factor analysis to test for the existence of two latent constructs psychological well-being and perceived isolation. For each, a linear growth model using mixed-effects will be estimated to examine both, whether there are differences in rates of change between intervention conditions and whether there are mean differences at specific times. The primary test will be the contrast for mean differences at the 9-month assessment. We will also examine whether differences exist at month 6. As noted in the power, we will examine residence-type differences in the intervention impact over time and if apparent, then test within residence-type. Also, if the intervention significantly impacts both social support and wellbeing, we will also test whether social support mediates the effect of the intervention on wellbeing. The mediation model estimates the effect of the intervention on the social support (path a) and the effect of the mediator on the well-being (path b). There is significant mediation if the product of these two paths (a*b) is greater than zero. Statistical significance will be assessed using bias-corrected bootstrap confidence intervals on the product terms, the most powerful test of mediation. Because slopes of growth curves are calculated on concurrent times, there is not temporal precedence between growth curves on the same time frame. We will reformulate the change model in a cross-lagged panel framework to examine temporal effects in the mediation models. In the primary hypothesis tests, if we find significance for any of the latent constructs we will decompose these effects into their constituent parts. Under other aim, will utilize the same linear latent growth curve approach but the dependent measures will be: computer attitudes, and proficiency and technology uptake. We realize that there will be mediators as well as moderators (e.g. gender, ethnicity) on particular analyses, which will can be incorporated into the model using Mplus. We will obtain information on usage data on the PRISM system over time, perceptions regarding the usefulness and usability of the system and interface design issues using standard questionnaires developed during PRISM.

Overall, all the study personnel who handle the data completed the CITI course. All the identifying information is removed from the rest of the data as soon as it reaches the Center on Aging. Only the study coordinator or designee has access to the password protected identifying information of the participant. The signed informed consent forms are stored in a separate double locked room. E-mail encryption is required when emailing any sensitive data. During transmission of large data files, we will use the "securesend".

## 8) **Risks to Subjects***

Phase 1 & 2: User Testing and Training Script testing Phase

These 2 phase involve completing paper and pencil questionnaires and interacting with PRISM 2.0 OR tablet. The completion of questionnaires should not cause any discomfort for the

participants or expose them to any medical/physical risks. The interaction with PRISM 2.0 OR tablet are between the participant and the RA. We don't anticipate participants feeling discomfort or expose them to any medical/physical risk either.

Phase 3: Trial Phase

This phase involves randomly assigning participants to Tablet or PRISM 2.0 system condition. Participants will be completing questionnaires as part of the assessments. They will be learning to use the Tablet and PRISM 2.0. The completion of questionnaire should not cause any discomfort or expose participants to any medical or physical risks. The interaction with the computer tablet should also not create any discomfort. All the data will not have any identifying information

A breach of confidentiality would be our most concerning risk; however, our team is experienced in conducting behavioral studies. Other risks include distress in answering questionnaires, as well as fatigue and boredom during the focus group sessions.

In our opinion, all the phases are a no greater than minimal risk study.

## 9) Potential Benefits to Subjects*

There is no direct benefit to participants. Participants will be expose to PRISM 2.0, which is not a marketable product for participants. Through which, they might become more socially connected and less isolated.

## 10) Vulnerable Populations*

The study involves Normal, healthy volunteers who are capable of providing consent to participate in the study.

## 11) Setting

The study-related activities for this phase will take place at the participant's home.

## 12) Resources Available

All the study personnel have their CITI certificate. The PI holds a weekly meeting with the study coordinator and data manager to review the progress of the study. At the same time, there are weekly meetings on data management and recruitment of participants. There is also a weekly clinical team meeting of assessors who are working one-on-one with the participants to monitor and review the progress of the participants.

The PI has extensive experience conducting research studies. Most of the members of this study are involved in other on-going studies at the Center. The Center has a computer dedicated to store and process the data. It also has secure room and cabinets to store study-related documentation. In addition, the study team is composes of assessors who are fully bi-lingual. They are fluent in both English and Spanish, thus capable of implementing the study in either language.

## 13) Prior Approvals

NA

## 14) Recruitment Methods

We don't have any recruitment/promotional material for Phase 1 of the study as we will be re-contacted participants who gave us consent before.

As we are ready to embark on other phases of the study, we will submit their corresponding flyers/promotional material for your approval.

Once potential participants learn of the study, they will phone the recruitment phone line. A brief telephone interview will conducted. If these participants are eligible for the study, they will then be scheduled for the baseline assessment.

This phase involves randomly assigning participants to the Tablet or PRISM 2.0 system condition. We included the study brochure/promotional material in the eProst. Upon the approval of such material, we will distribute them in the facilities (Assisted Living and Independent Living Facilities) and in the community. The facilities are our main source of recruitment. Interested participants will reach out to our research team via phone or email.

We will work closely with activities coordinators of these facilities so we can attend their events. We will present the study to residents while they attend activities at the facilities.

We also plan in including a short of blurb of the study (attached in eProst) in the newsletters that facilities distribute to residents.

Participants will receive financial compensation for completing assessments. There are a total of 3 assessments @ $30 each. Participants will receive $20 for completing the 12$^{th}$ month telephone follow-up. A total of $110 will be given to participants who complete all the assessments and the follow-up. Participants who are disqualified during the baseline visits (1$^{st}$ assessment) will receive $20. Participants who quit in the middle of the baseline assessment will receive $10.

## 15) Local Number of Subjects

We anticipate to have a maximum of 20 participants in Phase 1 (10 for each part – A & B), and 10 participants in Phase 2. For Phase 3, we anticipate enrolling a maximum of 300 participants across all sites.

## 16) Confidentiality

This study does not collect specimens. The data are questionnaire based and participants will be completing them online using a secure and unique log. All the data will be stored and secured using the procedure implemented by the Center for Cognitive Neuroscience and Aging. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

The hard copy data will be stored in a double locked office at the Center in the Mental Health building. The electronic and audio recorded data/interview will be kept in server computer at the Center as well. The data will be backed-up on a regular basis and the copies will be kept in a double locked office at the Center. Only study-related staff (listed in the IRB protocol) will have access to the data.

The online data will be collected on Qualtrics (the University has approved this survey/data collection service and has a subscription to it). Connections to the server are 128-bit

SSL encrypted. Minimum levels of password complexity will be enforced. The Tablet will be locked down, requiring a 4-digit PIN.

## 17) Provisions to Protect the Privacy Interests of Subjects

During the informed consent process, participants are made aware of who will have access to the study data (see section of Confidentiality). The participants are instructed to sign the Informed Consent Form only when he/she is completely satisfied with the information in the ICF, and all his/her questions are answered fully. We will not release participant information to anybody who is not listed in the Confidentiality section of the ICF.

## 18) Consent Process

The research team will not use undue influence or manipulation in order to recruit study participants. Our team has extensive experience in recruiting this population and is aware of the ethical conduct necessary to protect human subjects in research. They are all CITI certified. There is weekly meeting to monitor recruitment activities to discuss and review recruitment practices and efforts. Most of the members of the research team who have an active role in the conduct of the study (screening, assessment, and conducting the study) will also be involved in the recruitment and consenting process.

The study involves adults who have the capacity to consent. These potential participants are able to read and comprehend the information written in the Informed Consent Form. Questions will be answered and addressed accordingly. Therefore, not additional process will be used to obtain consent from them.

We are requesting a waiver of signed consent for our telephone pre-screening. The telephone pre-screening consists of asking participants questions to determine whether they are eligible for the study. At this point, it is not feasible to obtain a signed informed consent form. The RA will obtain a verbal consent (see the telephone pre-screening script) from the participant before proceeding with the questions of the telephone pre-screening.

We will obtain a written Informed Consent Form (ICF) from participant during the first home visit. Upon the arrival of the RA to the participant's home, he/she will introduce him/herself to the participant as a member of the research team. The RA will have 2 copies of the ICF. The RA will read and go over each section of the ICF with the participant. The RA will ask participants questions such as what is the duration of the study? How many time will I be coming to your house? What is the financial compensation for that you will receive for today's visit? to make sure he/her understands the consent form. In addition, the participant is made aware that this is a research study and their participation is voluntary. After reading the ICF, the RA will ask and clarify questions that participant might have. Once all the questions have been answered to the satisfaction of the participant, the RA will ask the participant to sign and date both copies of the ICF. The RA will sign and date as the person obtaining consent. The participant will keep one of the signed and dated ICFs for his/her records.

The RA will not start any study-related activity until a signed ICF is obtained from the participant.

## 19) **Process to Document Consent in Writing**

This phase involves randomly assigning eligible participants to Tablet or PRISM 2.0 system condition. Participant's eligibility is determined during telephone pre-screening. As described in above section, we are asking for waiver of signed consent form because it is not feasible to obtain it during a telephone. We will obtain a signed Informed Consent Form (ICF) during the first home visit.

The informed consent process of this phase can be done in English or Spanish depending on the language of preference from the participant.

The participant is asked to read the ICF and encouraged to ask questions. If the RA detects the participant is having difficult reading the ICF, the RA will read with the participant alternating paragraphs. In order to assess whether the participant comprehends the ICF, the RA will ask the participant to paraphrase the content of the ICF or random questions (see above section).

Participant will sign and date the ICF in the presence of the RA once all his/her questions and concerns have been answered. The ICF will be stored in a separate location from the rest of the study data.