University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.*
    - *For exempt research: Sections 31 and 32 do not apply.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response:

Intervention Group:

Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response: Providing support to caregivers of frail older adults with cognitive impairment to reduce caregiving burden

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: Machiko R. Tomita

Rehabilitation Science

(716) 829-6740

Machikot@buffalo.edu

VERSION:

Include the version date or number.

Response: V.2

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: The grant proposal to Ralph Wilson Jr. Foundation is attached.

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: 623 Kimball Tower, University at Buffalo

Address: 623 Kimball Tower, UB, 3435 Main Street, Buffalo, NY 14214

Department: Rehabilitation Science

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research.

Response:

The purpose of this project is to develop and test affordable, effective strategies to reduce caregiver burden and associated negative effects (e.g., depression and fatigue) and to increase caregivers' satisfaction and self-efficacy, so that they can continue providing home-based care to their care recipients (CRs) who are members of the Program of All-inclusive Care for the Elderly (PACE). This project will connect PACE organizations and university occupational therapy (OT) graduate level curriculum to produce a practical, sustainable care model. In this project, a research component pertains to assess effectiveness of OT interventions

1.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

We have three reteach questions and two hypotheses.

1. What are challenges that caregivers are facing in caring for their care recipients?

2. Which solutions were accepted and effective?

3. The intervention group will reduce caregiver burden and depression, while the control group will not.

4. The intervention group will increase the scores of positive aspect of caregiving and self-efficacy while the control group will not.

5. At 6-months after intervention, does the effect of our intervention exist?

In addition, we will identify the rate of care recipients who live in the community opposed to moving to a nursing home for both groups, and the number of falls and emervengy visits of care recipients.

Scientific Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

Primary endpoint for the study is the reduction of caregiver burden and depression. Secondary endpoints is the improvement in positive aspect of caregiving and self-esteem.

2.0 Background

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response:

Current research shows that caregiver burden is an issue of concern for this population, as the depression that often accompanies burden can be debilitating for caregivers (Dean & Wilcock, 2017; Etters, Goodall, & Harrison, 2007). When caregivers experience high levels of burden, their care recipients are much more likely to be placed in a nursing home (Etters, Goodall, & Harrison, 2007). Levels of caregiver burden are higher if care recipients have dementia (Prinquart & Sorensen, 2007), because these caregivers face more difference challenges than caregivers for older adults without dementia. Caregiver burden tends to be the result of care of a recipient who has impairments in function, behavior, cognition, and/or psychological factors such as depression (Paradise et al., 2014). Caregivers are often unaware of how to provide care for their care recipients when they are struggling with the symptoms of AD, especially when they are having difficulty with activities of daily living (ADLs : Seeher, Low, Reppermund, & Brodaty, 2013). Providing support, education, and training to caregivers that address their individual challenges has the potential to decrease the burden felt by caregivers and as a result increases both the caregivers and care recipients quality of life.

Current research identifies specific interventions that are effective. Pharmacological drug interventions for the care recipient have been shown to relieve caregiver burden (Beinart, et. al., 2012). This information, although helpful for understanding the population, is more specific to

addressing the medical needs of the care recipient rather than the caregiver. Another finding from previous research is that interventions that are individually customized to the care recipient and caregiver's needs are more effective than generalized interventions (Pinquart & Sörensen, 2006). There are interventions and educational programs for caregivers that have shown to be effective (Austrom & Lu, 2009). Support groups are effective to help caregivers, but currently no program supports caregivers by instructing how to provide care for care recipient's ADLs, which is the core of caregiving tasks. Occupational therapist (OT) can apply their knowledge in providing care for patients with dementia to caregivers. In doing so, we realize that practical solutions for the challenges that caregivers are facing can be developed using a caregiver-centered approach, rather than a top-down approach. Therefore, individualized interventions for the caregiver determined on a case-by-case basis by a team of gerontologists, occupational therapists, and occupational therapy students, which can be finalized by the input from caregivers, may lead to a better outcome for caregiving situations. In addition we explore if positive effects of caregiver support will last six months after the intervention beucase it will find if continuous support is needed for this target population.Currently, related studies do not exist.

2.2 Include complete citations or references.

2.3

Response:

Austrom M G, & Lu,Y. (2009). Long term caregiving: helping families of persons with mild cognitive impairment cope. Current Alzheimer Research, 6 (4), 392-398.

Beinart N, Weinman J, Wade D, & Brady R. (2012. Caregiver burden and psychoeducational interventions in alzheimer's disease: A review. Dementia and Geriatric Cognitive Disorders EXTRA, 2(1), 638–648.

Dean K & Wilcock G. (2012) living with mild cognitive impairment: the patient's and carer's experience. International Psychogeriatrics, 24(6), 871-881.

Etters L, Goodall D, & Harrison BE. (2007) Caregiver burden among dementia patient caregivers: A review of the literature. Journal of the American Academy of Nurse Practitioners, 20, 423-428.

Paradise M, McCade D, Hickie IB, Diamond, K, Lewis S, Naismith S. (2014) Caregiver burden in mild cognitive impairment. Journal Aging & Mental Healht, 19, ., http://dx.doi.org/10.1080/13607863.2014.915922.

Pinquart M & Sörensen S. (2006) Helping caregivers of persons with dementia: which interventions work and how large are their effects? International Psychogeriatrics, 18(4), 577–595.

Pinquart M, Sorensen S (2007). Correlates of physical health of informal caregivers: a meta-analysis. J Gerontol B Psychol Sci Soc Sci. 62(2):126–37.

Seeher K, Low,L-F, Reppermund S, & Brodaty H. (2013). Predictors and outcomes for caregivers of people with mild cognitive impairment: A systematic review. Alzheimer's & Dementia, 9, 346-355.

3.0 Study Design

3.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

We will use a qualitative method to understand difficulties that caregivers are facing and to document solutions and their implementation process; and a quantitative method using a randomized contoured trial with pre-, post- and follow-up experimental design. A treatment group will receive a 1 to 2-month interventions to solve caregiving challenges, and a control group will receive usual support. Assessments will be conducted at baseline, 2 months (posttest), 4 months (follow-up), and 6 months post intervention.

4.0 Local Number of Subjects

4.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: 60

4.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: 75

4.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

There are approximately 300 PACE enrollees/members in Eire and Niagara Counties. Among them 50% are having cognitive impairments. Of 150, we expect about 1/2 to 2/3 of them have caregivers who are experiencing challenges in caregiving; therefore 75 to 100 caregivers. The sample size for this study was determined by a power analysis based on the study similar to ours (Kamiya et al., 2014). The effect size found in the article was d = 0. 65. We will use a directional hypothesis; therefore, we set $\alpha_1 = .05$, and in order to achieve 80% of statistical power, we will need 30 participants in each group, therefore 60 in total. Expecting 25% attrition, we will recruit 75 participants.

Kamiya M, Sakurai T, Ogama N, Maki ., & Toba K. (2014). Factors associated with increased caregivers' burden in several cognitive stages of Alzheimer's disease. Geriatrics & Gerontology International, 14(2), 42-55.

5.0 Inclusion and Exclusion Criteria

*5.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

- Caregivers of community-dwelling older adults (55 and over) who are member of the PACE
- Adult 21 years or older
- Living with the care recipient or within a distance so that they can visit him/her minimum once a week
- Cognitively intact (can recall three words immediately and 3 minutes later)
- Competent in English

*5.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

- Distant caregivers who does not help care recipients' activities of daily living (ADL) or instrumental activities of daily living (IADL).

5.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☒ Pregnant women

☐ Prisoners

Caregivers may be pregnant. We will not exclude them.

*5.4 Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

One instrument (Positive aspect of caregiving) is only available in English. To fully understand caregivers' challenges and convey solutions, our current study OT graduate students are not competent enough in other languages to provide interventions. We do not have budget to hire interpreters.

6.0 Vulnerable Populations

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

*6.1 For research that involves **pregnant women,** safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response: Caregivers may be pregrant women. The procedures in the study are such that they present no added risk to the mother or feturs.

☐ **N/A**: This research does not involve pregnant women.

*6.2 For research that involves **neonates of uncertain viability or non-viable neonates,** safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

*6.3 For research that involves **prisoners**, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

*6.4 For research that involves **persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")**, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*6.5 For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

*6.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

In this study, no participants will be people who require special consideration.

7.0 Eligibility Screening

*7.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response:

A screening document is included in an invitation letter and is described in 9.0 Recruitment Methods. In addition, when we make a phone call, we will also ask screening question. This is also attached.

☐ **N/A:** There is no screening as part of this protocol.

8.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

8.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

An invitation letter will be mailed to all caregivers of PACE enrollees who have cognitive impairment from the PACE. (The letter is attached.) Caregivers who are interested in the study will return the letter to the PI.

8.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response:

Caregivers who are interested in the study will contact the PI. They will not be able to stop receiving the invitation letter from the PACE, but they control access to them by contacting or not contacting the PI; therefore their privacy is protected.

8.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

The invitation letter and a flyer are attached. They will be mailed together.

9.0 Procedures Involved

*9.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

After obtaining approval from the IRB, UB OT graduate students (OTGS) will be educated and trained for 2 months prior to the start of the intervention. They will study the protocol, interview methods, and interventions. PACE rehabilitation, department staff will also be educated

about the protocol and they will mail an invitation letter and a flyer to caregivers of person with dementia. These records are readily available at the PACE as a standard record keeping procedure.

Interested caregivers will contact the PI and will be screened for eligibility for the study.

OTGS will make an appointment to visit participants. While reading a consent form, an OTGS will explain the study in detail and make sure that the caregiver understand the content. Their right to withdraw from the study without penalty will be explained. After obtaining written consent, t a structured interview will take place about 30 minutes. It starts with asking demographic questions, care recipient's cognitive and physical function, levels of assistance the caregiver is providing, and followed by questions about caregivers. This section will ask caregiver burden, fatigue, depression, positive aspect of caregiving, and self-efficacy in caregiving.

The OTGS will talk with caregivers to understand problems in depth. Examples may include difficulty in (a) understanding the disease development process and its consequences; (b) assisting care recipient (CR)'s ADL, IADL, and communication; (c) coping with CRs' undesirable behaviors (e.g., non-use of a stair glide, pulling a cord to turn off lights, reluctance in changing clothes and washing hair, inactivity and lack of motivation in daily routine); (d) maintaining caregivers' health and strength; (e) coordination of care among family members, and (f) having own time. In addition, we will specifically address fall prevention because PACE enrollees have a high fall rate.

When the detailed challenges were documented, the OTGS may recommend some solutions, if she has, such as educating the process of Alzheimer's disease and suggesting an assistive device, good grip utensils.

At the end of the invierview, the participant will be paid $20.00.

The UB geriatric team including OTs, a gerontologist, and OTGS will brainstorm to develop solutions to identified problems. Within a week, these solutions will be presented to the participant and the OTGS and the participants will decide final solutions that the participant will perform. We use a caregiver-centered approach to facilitate their motivation to continue their care. The proposed approach will emphasize working collaboratively with caregivers to identify challenges and individualized strategies for each caregiver to solve specific problems. This is a different approach from the traditional therapist-client relationship, in which therapeutic prescriptions are made and provided by OTs to their clients.

Agreed-upon solutions will be reported to the PACE, especially if suggestions involve CRs. If assistive devices are needed, the PACE will provide them along with proper training for use.

Example interventions include: (a) didactic education about diseases; (b) the use of errorless techniques to improve assistance for CR's ADL,

IADL, and communication tasks; (c) the use of incentives (e.g., providing a favorite scented shampoo, going for an ice cream after going to a hair stylist, having a snack or short game to prevent going to bed right after dinner); (d) use of the Buffalo Functional Exercise for strengthening (a home-based exercise developed for PACE by the PI and shown to be effective in preventing falls, as reported by the NY Dept. of Health; attached); (e) use of a schedule/calendar on a computer, cell phone and/or blackboard in CR's home to coordinate caregiving tasks for family members; (f) suggesting more frequent PACE daycare visits or use of a nearby PACE-recommended daycare center; and (g) home safety suggestions using the Home Safety Self-Assessment Tool (HSSAT) to prevent falls in CR's home environment. We expect that more customized solutions will arise from this project.

A month after initial assessment, OTGS will contact CRs for follow-up and 2 months later, the posttest will be administered. At 4 months, follow-up interview will occur. The number of home visits (4-6) will vary depending on case. Finally 6 months after the intervention, a pohne call will be made, asking the same quesaitons before and the number of falls and mergency visits of care recepitns in the past 10 monhts. After each interview, a participant will be paid $20. (The total maximum is $80).

9.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

The outcome measures will use established instruments. To measure caregiver burden, 12-item Zarit Burden Interview (ZBI), for depression, 20-item Center for Epidemiology Study-Depression (CES-D) will be used. Positive Aspect of Caregiving has 9 items. Self-esteem and fatigue questions will use a visual analog scale from 1 to 10. In addition, items of activities of daily living (ADL, e.g., eating, dressing, and toileting) and instrumental ADL (IADL, e.g., meal preparation, housekeeping) that caregivers are assisting will be identified. We do not assess or provide interventions for CRs directly, but we ask caregivers about CR's cognitive levels using Global Deterioration Scale, and functional levels using FIM to asses ADL and OARS' IADL. We also ask if care recipients fell or visited an emergency room.

9.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response:

The assessment form is attached.

9.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response:

We will not use other sources or records. But if the cause of cognitive impairment is not clear, we will ask the PACE to provide it for us. This is written in the consent form.

*9.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response:

We will share the solutions with caregivers but not the score of outcome measures, unless the score of CES-D is 15 or higher (indicative of depressive symptoms). This will be shared with PACE because their program include not only care recipients but also their caregivers.

*9.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response:

At the assessment, if a caregiver scores 15 or higher for the CES-D, the interviewer will inform him/her about the result and contact the PI immediately. The PI will report it to the PACE immediately. The PACE will respond to this situation according to their policy. The policy for caregivers is instituted because they are integral part of the care recipient's ability to continue living in the community. Other assessed results will not be shared with participants, but aggregated data will be shared with the PACE. This include problems and solutions.

10.0 Study Timelines

10.1 Describe the anticipated duration needed to enroll all study subjects.

Response:

The duration need to enroll all participants is 19 months.

10.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response:

Each participant intervention is 1-2 months and it will take 30 – 45 minutes for each of 4 time assessments. From the beginning of the contact to the end of 4h assessments, it ill be about 10 months.

10.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response:

2. 5 years

11.0 Setting

11.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response:

Care recipients' home where OTGS can observe caregivers' difficulty in caring for the care recipients, or caregivers' home. All of them are located in either Eire County or Niagara County. Other activities will take place in a conference room in the Department of Rehabilitation Science at UB. The final assessment will be conducted through a phone call.

11.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

Residential places where caregivers are members of the PACE. OTGS will be trained for safety and regulation at the PACE under the status of volunteer.

☐ **N/A:** This study will not be conducted outside of UB or its affiliates.

12.0 Community-Based Participatory Research

12.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

12.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

13.0 Resources and Qualifications

*13.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

Machiko R. Tomita, PhD, Clinical Professor at the UB Department of Rehabilitation Science, School of Public Health and Health Professions is the PI. Dr. Tomita possesses expertise in home-based exercise, function, and health behavior in older adults, and a record of accomplishment of conducting federally funded studies to improve older adults' health and quality of life through promoting their independence. She collaborated with the PACE in previous study on fall prevention. In addition, she authored two articles on international caregivers on individuals with Alzheimer's disease. Co-Investigator Turquessa Francis, Ed.D. OTR is an experienced geriatric occupational therapist whose specilaity is fall prevention in older audlts. Interviewers are all graduate level of occupational therapy students who completed occupational therapy courses and passed level I (1 week each) and level II (3 months) field work. They will be supervised by the PI and co-PI. Therefore, they are all qualified to conduct this research.

Describe other resources available to conduct the research.

13.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response:

The PI will spend 0.11 FTE and the Co-I will spend .05 FTE, extra in addition to regular student's project time (3 credits per semester). Since this project is tied with a students' mandatory research group project, students will spend regular time, 3 hours/week and extra 2% for this project for extra record keeping for this research purpose. In addition, a research assistant will spend 0.2 FET for two calendar years. These efforts were justified and accepted by the School and the grant giver.

Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response:

The PACE has medical doctors, nurses, physical therapists, occupational therapists, a speech and language therapist, and a dentist. They will be available when specific relevant questions arise.

13.3 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:

We set aside two months prior to start the project to make sure all parties are familiar with the protocol. Each OTGS will be tested by the PI for the procedure and how to communicate with caregivers, methods to collect data.

We will be communicating with rehab directors at the PACE. The PI will explain the protocol in detail to the rehab facility members in two meetings. The protocol has been accepted by three facilities of the PACE prior to submitting the grant proposal.

14.0 Other Approvals

14.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

We recived funding from the Ralph Wilson Jr. Foundation between July 1st, 2017 and June 30th 2018. .. The revisin/addition was requested by the evaluator of the foundation and approved on October 2nd, 2018.

☐ **N/A:** This study does not require any other approvals.

15.0 Provisions to Protect the Privacy Interests of Subjects

15.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response:

A participant only meets with a study interviewer in his/her designated place where no one can overhear and he/she are free to refuse to answer any questions that they do not feel comfortable answering. Therefore, patricians' privacy will be protected.

15.2 Indicate how the research team is permitted to access any sources of information about the subjects.

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response:

Obtaining the IRB and participants' permission in a consent form allows to access medical information revealed by the PACE, if it is necessary.

16.0 Data Management and Analysis

16.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

For two hypotheses, we first analyze a linear trend of dependent variables over time. If they are linear, we will use Generalized Estimating Equation to compare the two groups' slopes. A main effect and an interaction effect will be examined. If it is not, we will use Repeated Measures ANOVA with a between-factor. The contrasts within a group and the difference between groups will be performed as post hoc tests. To answer the last reseahc question to find the difference between

the 4-months data and 6 month after intervention (or at 10 months), we will use Repaeated meausres ANVA with a between-factor.

To answer research questions, we will list all challenges for both groups and solutions for the treatment group. The effectiveness of solutions will be evaluated using a Likert Scale (from very effective to not effective at all) and percentages will be reported. For the rate of continued community, living at 4 months will be tabulated for both groups and a chi-square test will be used. The number of falls and emergency visits will be compared for these two groups using Mann Whitney U-test.

The significance level for primary analyses will be set at .05. SPSS 26.0 will be used for statistical analyses.

16.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response:

The sample size for this study was determined by a power analysis based on the study similar to our study (Kamiya et al., 2014). The effect size found in the article was d=. 65. We will use a directional hypothesis; therefore, we set α 1 = .05, and in order to achieve 80% of statistical power, we will need 30 participants in each group, therefore 60 in total. Expecting 25% of attrition, we will recruit 75 participants.

Kamiya M, Sakurai T, Ogama N, Maki ., & Toba K. (2014). Factors associated with increased caregivers' burden in several cognitive stages of Alzheimer's disease. Geriatrics & Gerontology International, 14(2), 42-55.

16.3 Describe any procedures that will be used for quality control of collected data.

Response:

The data will be collected using a pen and paper and transferred to a computer software program (SPSS) file. The transferred data will be verified by an OTGS who is different from the data collector for missing data and correctness of data.

Confidentiality

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

16.4 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) ***and*** *electronic files.*

Response:

Data in a paper form will be stored in a locked file cabinet in room 623 Kimball Tower where only the PI can access with a key. This is separated from the identifiable information. Transferred data into SPSS will be stored in the UB Box, which is password protected and encrypted. Only study OTGS and PI can access the file with permission and a password.

The only link between personal identifiers such as name, address, phone number and data will be an ID number.

16.5 A. How long will the data be stored?

Response:

Hard copies will be destroyed after two years of the study period. The SPSS data will be stored for 10 years for publication.

16.6 A. Who will have access to the data?

Response:

The study OTGS who collect data and the PI.

16.7 A. Who is responsible for receipt or transmission of the data?

Response:

The study OTGS who collect data and the PI.

16.8 A. How will the data be transported?

Response:

A person who collect data will transfer the data form hard copy to a SPSS database in the SPHHP computer lab and store the data in the UB BOX. Another person who verify access the file in the UB Box.

B. Confidentiality of Study Specimens

Describe the local procedures for maintenance of confidentiality of ***study specimens****.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)* ***Does this mean Section 17.0?***

16.9 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

16.10 B. How long will the specimens be stored?

Response:

16.11 B. Who will have access to the specimens?

Response:

16.12 B. Who is responsible for receipt or transmission of the specimens?

Response:

16.13 B. How will the specimens be transported?

Response:

17.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

17.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response:

We will not periodically evaluate the data collected but we will collect data every 2 months for three times. The study will identify depression. If the total score of CES-D is 15 or higher at the time of interview, this will be reported to the participant and the PACE for an appropriate intervention.

17.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response:

The total score of the Center for Epidemiology Study-Depression will be used to detect depression, which is a considered mental illness.

17.3 Describe any safety endpoints.

Response:

The CES-D total score of 14 or less (not depressive) and 15 or higher (indicative of depressive symptom). One of the purpose of the study is to decrease the CES-D score.

17.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

Face-to face interviews.

17.5 Describe the frequency of safety data collection.

Response:

Three times in 4 months.

17.6 Describe who will review the safety data.

Response:

Study OTGS and the PI

17.7 Describe the frequency or periodicity of review of cumulative safety data.

Response:

We do not have cumulative safety data. When each time we interview participants, we will review the data.

17.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

The sum of 20 item CES-D scores will be used.

17.9 Describe any conditions that trigger an immediate suspension of the research.

Response:

If the CES-D score is 15 or higher, it will be reported to the PACE for possible intervention, in accordance with their policy. We do not have any conditions that will be used for immediate suspension of the participant form our research.

18.0 Withdrawal of Subjects

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*18.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response:

We will not withdraw a participant from the research without their consent.

18.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

If a participant decide to withdraw for the study, he/she will indicate it to an OTGS at the interview and the PI will confirm the wish through a phone contact with the participant.

18.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

After the orderly termination, the data that had been collected until the withdrawal will be retained and analyzed. This information is included in the informed consent.

19.0 Risks to Subjects

19.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response:

While being asked about depression in the past week, participants may be upset. We consider this as a minimal risk. But if the data shows that the participate is depressive, we will take an immediate action described above.

While a caregiver is helping the care recipient's activities of daily living using a new technique that are learned from us, such as a new transfer method, they may make a mistake and fall and have an injury. However, prevention of falls is one our study purpose.

19.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response:

If a participant appears to be upset, the interviewer (OTGS) will ask if he/she would like to continue the interview or not. If they wants to continue after

a little rest, the interview will be resumed. If not, an interview at another time will be asked to complete the interview and make an appointment. In addition, if he/she scores 15 or more in the total CES-D, it will be informed to the participant and the PACE. The PACE may inform the PI about withdrawal of the participant from this study. We do not know the PACE criteria for the decision, but we will follow the PACE's decision.

Physical injury may occur while assisting care recipients' activities of daily living, but the purpose of the study is to prevent that. Any newly learned methods may cause discomfort or a fall, if the method is applied in a wrong way. Therefore, OTGS will show an intervention and caregivers will practice it until they become comfortable. An illustrated instruction will be provided for caregivers, if necessary or requested.

*19.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

Assisting transfer from a bed to a standing position and getting up from a couch.

If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: N/A

19.4 If applicable, describe risks to others who are not subjects.

Response:

It is possible that caregivers' response to the study may upset their care recipients. Therefore, the structured interview will take place that the care recipient is not present.

20.0 Potential Benefits to Subjects

20.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response:

The benefits to participants may include reduced caregiver burden and depression, increased positive aspects of caregiving and self-esteem to be an effective caregiver.

21.0 Compensation for Research-Related Injury

☐ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

21.1 ***If the research procedures carry a risk of research related injury,*** *describe the available compensation to subjects in the event that such injury should occur.*

Response:

There will be no compensation for research related injury.

21.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with ***different language regarding research related injury****, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

It is stated in the consent form. "If you injure while caring for your care recipient, we are not responsible and compensate for the injury."

All OTGS has malpractice insurance as a mandate.

Economic Burden to Subjects

21.3 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response:

There will be no cost for participating in this study.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

22.0 Compensation for Participation

25.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response:

Participants will be paid $20 right after each interview.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

23.0 Consent Process

23.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 27.0)*

23.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response:

The consent process will take place either caregiver (participant)'s home or the care recipient home; therefore, the participant has a total control to secure his/her privacy.

23.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response:

We will provide three opportunities for individuals to decide their participation in the study. First through an invitation letter, the second is the PI's initial phone call, and the third is a face-to-face conversation with an OTGS. At the last step, the consent form will be provided and they will be asked to read each section and have questions. All OTGS will have been trained to answer questions. During this consenting process, we will give sufficient time for participants to understand the study and ask questions. After they understood the study, they will be asked to sign the consent form.

23.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response:

After obtaining written consent for the initial interview, in the beginning of 2nd and 3rd interview, participants will be asked their willingness to be in the study or not. In addition, this study will involve phone contacts with participants to find whether solutions are working and make a next appointment. At that time, if we suspect unwillingness to continue to be in the study, we will ask their wish to withdraw from the study. This will be followed by the PI's contact with them for confirmation.

23.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 26.8)

23.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response:

23.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

23.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

23.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

23.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

23.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

Response:

- *If assent will not be obtained from some or all subjects, provide an explanation of why not.*

Response:

*23.12 Describe whether **assent of the adult** subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

*23.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

*23.14**For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

23.15 Describe whether parental permission will be obtained from:

Response:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*23.16 Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*23.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

23.18 When assent of children is obtained, describe how it will be documented.

Response:

24.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

24.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

24.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

25.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

25.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

The consent form is attached.

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

26.0 Multi-Site Research (Multisite/Multicenter Only)

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

*26.1 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*

- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

26.2 Describe the method for communicating to engaged participating sites:

- *Problems*
- *Interim results*
- *Study closure*

Response:

26.3 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

26.4 If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

Response:

27.0 Banking Data or Specimens for Future Use

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*27.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

27.2 List the data to be stored or associated with each specimen.

Response:

27.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response:

28.0 Drugs or Devices

☒ **N/A:** This study does not involve drugs or devices. This section does not apply.

28.1 If the research involves drugs or devices, list and describe all drugs and devices used in the research, the purpose of their use, and their regulatory approval status.

Response:

28.2 Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

Response:

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

28.3 Identify the holder of the IND/IDE/Abbreviated IDE.

Response:

28.4 Explain procedures followed to comply with FDA sponsor requirements for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response:

29.0 Humanitarian Use Devices

☒ **N/A:** This study does not involve humanitarian use devices. This does not apply.

29.1 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.

Response:

29.2 For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

Response: