VCU Office of Research and Innovation

Date: Tuesday, March 1, 2022 5:23:59 PM Print Close

ID: MS4_HM20020066 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Mark Baron
2. * **Study Title:**
   Safety and Efficacy of State-of-the-Art Exoskeleton Technology to Improve Mobility in Parkinson's Disease
3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**
4. * **Please select the primary department or center that this study is being conducted under:**
   Neurology
5. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI
HM14555	Parkinson's Disease and Movement Disorders Center Data Registry	Brian Berman

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Baron	Mark	msbaron@vcu.edu	8048289350	
Blackwell	GinaMari	blackwellgg@vcu.edu		

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device
   - ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   - ○ Center or Institute Administrative Grant Review
   - ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

ID: MS4_HM20020066 View: SF2 - Federal Regulations

Federal Regulations

1. * **Is this a FDA regulated study?**

   FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
   Check Yes if
   • the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,
   • the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR
   • the study does not involve a test article but intends to provide safety or efficacy data to the FDA.

   - ● **Yes** ○ No

2. * **Indicate the FDA regulated product(s) this study involves:**
   - [ ] Drug
   - [x] **Medical Device**
   - [ ] Biologic
   - [ ] Dietary Supplement
   - [ ] Food/Food Additive
   - [ ] Color Additive
   - [ ] Electronic Products for Human Use (radiation producing)
   - [ ] Other

3. * **Is this study supported by the Department of Defense (DoD):**
   - ○ Yes
   - ● **No**

4. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**
   - [ ] Department of Education
   - [ ] Department of Justice
   - [ ] Environmental Protection Agency
   - [x] **None of the above**

ID: MS4_HM20020066 View: SF2 - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**
   - ● **VCU IRB**
   - ○ WCG IRB
   - ○ NCI Central IRB
   - ○ Advarra IRB
   - ○ Other IRB

2. * **Is this study transitioning to review by another IRB?**
   - ○ Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
   - ○ Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
   - ● **No or not applicable**

ID: MS4_HM20020066 View: SF2 - Review Setup

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ● **Bio-Medical Research**
   - ○ Social/Behavioral/Education (SBE) Research

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   In-person interactions / interventions with participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   No, not possible to convert to remote activities

4. * **Does this study involve greater than minimal risk:**
   - ● **Yes** ○ No

5. * **Review type requested: (subject to IRB approval):**
   - ● **Full Board**

- ○ Expedited
- ○ Exempt

6. Is this study initiated by a VCU investigator or a sponsor:

- ● **VCU Investigator initiated**
- ○ Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.

Possible or minimal direct benefit to individual participants
Scientific benefit

ID: MS4_HM20020066 View: SF2 - Initial Setup Complete

Initial Setup Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Background, Rationale and Goals

Background, Rationale and Goals

1. * Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.

The extent of disability in late stage PD limits the effectiveness of medicines and physical treatment interventions. When patients become dependent on walkers for mobility or have progressed to the point of being wheelchair or bed bound, there is essentially no evidence for interventions to support recovery, much the less maintain current function.1 Typical therapy paradigms at this stage are compensatory and focus on caregiver training with reduced patient autonomy.2,3,4 Robotic-assist gait training (RAGT) has been extensively applied as a remarkable therapeutic modality, such that it is enabling highly motivated people with devastating neurologic injuries and disorders associated with near complete motor loss to regain independent ambulation. Currently, RAGT is targeted to a highly restricted population, including those with spinal cord injuries, strokes, and multiple sclerosis.5 RAGT has evolved from treadmill-based training to over ground walking by means of portable robotic exoskeletons. Further, lightweight assisted devices intended for daily wear are being developed by multiple technology companies. These devices are designed to provide a passive force to assist in mobilizing the legs and to give the additional force necessary to, for example, complete a full step, aid climbing stairs or traverse a curb. Despite the remarkable potential for this cutting-edge technology to transform the lives of people with PD and other parkinsonisms, these devices are not being adequately investigated in this population. FDA approval has not yet been obtained for these over ground exoskeleton devices in our proposed population. We are, therefore, effectively the frontrunners in advancing the use of portable exoskeletons for PD and other movement disorders.

To date, RAGT has only been investigated in PD subjects using limited treadmill-based systems and these studies have only focused on those with retained independent ambulation. One such study determined that the Hocoma Lokomat® treadmill-based system was safe and well tolerated in patients with Hoehn & Yahr (H&Y) stages II and III when operated 3 times per week for 30 minutes per day at 2.2 ® 2.5 km/h. Participants experienced improvements in Tinetti Walking, Tinetti Balance, UPDRS Part III, and Geriatric Depression Scale (GDS); however, no effect was noted on 10-meter Walking Test (10MWT) or PDQ39.6 More recent case studies reported improved FOG following Hocoma Lokomat® training, but these studies again were focused on treadmill-based RAGT in patients who remained independent for ambulation.7

Studies in other patient populations have demonstrated training effects with treadmill based RAGT systems that typically lack carryover upon follow-up assessment.8 In comparison to RAGT treadmill systems which can perform

walking 100% passively, the increased intensity, salience, and variability in training environments afforded by over ground exoskeleton units are anticipated to yield appreciable greater therapeutic results. Patients will be able to negotiate an environment, rather than a closed course of a treadmill system, for greater engagement with changing scenery and stimulation. We recognize the importance of patient engagement and motivation as it pertains to motor control theory and neural plasticity.9 These features are crucial in retraining or maintaining a skill such as walking. Ultimately, due to the lighter weight of these portable exoskeleton devices, patients can be expected to use the devices for regular wear outside of the therapy environment. Home use is expected to not only produce better outcomes of mobility but also provide the greatest benefit to quality of life by improving or maintaining participation in family-based and community activities.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
Is the wearable exoskeleton assistive technology safe for people with debilitating movement disorders to use on a daily basis?

What is the potential efficacy of wearable exoskeleton assistive technology and will it be transformative for day to day functioning of those with debilitating movement disorders?

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Aim 1. To establish the safety of a portable exoskeleton for walking training in persons with PD.

We will measure safety as it pertains to the absence of or limited adverse events with training. We will assess via tracking of adverse events throughout training, including the number of "prevented" or "near falls" requiring physical assistance by the investigative training team.

Aim 2. To assess the efficacy of a portable exoskeleton for gait mobility and postural stability in persons with PD.

Intervention efficacy will be measured through comparative analysis of pre-, post- and durability assessments of mobility and impairment. We will assess walking capacity and benefit (and safety) to management of freezing of gait (FOG) with the Six Minute Walk Test (6MWT), and Ten-Meter Walk Test (TMWT), balance and postural stability with the Berg Balance Scale (BBS), disease severity with the Examination, part III of the Unified Parkinson's Disease Rating Scale (UPDRS), and impact on quality of life and activities of daily living, through the Parkinson's Disease Questionnaire (PDQ39) and the Parkinson's Disease Carer Questionnaire (PD-Carer). During measure of the 6MWT and TMWT, both aided by the exoskeleton and unaided (i.e. standard), additional data points will be collected through use of the APDM Mobility Lab wearable sensor system. Six sensors will be placed on specific landmarks to capture truncal and appendicular movement. Our team proposes the use of the following measures to best track proficiency of exoskeleton device use and net effect on FOG: cadence, gait cycle duration, gait speed, double support time, stance time, step duration, stride length, swing phase, toe out angle, stride length variability, arm swing velocity, arm swing range of motion, and anticipatory postural adjustment via APA duration, first step duration, and first step range of motion. These anticipatory postural adjustment measures are specific to initiation of gait, a critical event impacted by FOG. Additionally, measures of truncal sway will further strengthen our assessment of postural stability relative to dynamic walking.

At end of training, the 6MWT will be compared with and without the exoskeleton towards our goal of establishing an indication for long-term studies assessing in-home use. The 6MWT will be adminstered with standard instructions while also scoring FOG based on the criteria in the UPDRS items 3.10 (Gait) and 3.11 (Freezing of Gait) during 6MWT with and without the exoskeleton.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

We expect that mobile exoskeleton devices will provide a tremendous advancement for walking and bending assistance for people with PD and other movement disorders, permitting them to maintain a more normal lifestyle and quality of life. Portable exoskeleton devices can be expected to afford major advantages over current usage and dependence on walkers in those with advancing symptoms. For those however dependent on walkers for postural stability, the addition of an exoskeleton device will permit more effective ambulation at appreciable quicker speeds. For drastically lower cost than motorized wheelchairs, personal exoskeleton devices will circumvent or delay the need of motorized wheelchair dependence and associated deterioration and shorting of life in those with debilitating movement disorders.

While PD is itself a devastating condition, atypical forms of parkinsonism do not respond to medications and current therapies offer only modest benefits and so portable exoskeletons can provide people with these conditions new hope to maintain functional mobility. A longer term goal of this work will be to continue to modify these devices to be costumed for the individual.

5. * **Describe any potential for direct benefits to participants in this study:**
Patients may have increased mobility and/or other secondary benefits after completing the trial.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
n/a

7. **Upload a supporting citation list if applicable:**

ID: MS4_HM20020066 View: SF2 - Study Population

Study Population

1. * **Provide the maximum number of individuals that**

1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
AND/OR
2. You obtain any data/specimens about (regardless of identifiability)

at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
90

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
An overarching goal of this pilot study is to obtain estimates of the means and variances of all study measures to facilitate a power analysis for future extramurally funded clinical trials. van Belle proposed that a minimum of 12 observations should be used to calculate confidence intervals based on the t-statistic with n – 1 degrees of freedom.17 This rule is based on the fact that the half-width confidence interval for the mean decreases rapidly up to n = 12, at which point the decrease is less dramatic and the half-width curve begins to asymptotically decrease. Thus, the proposed sample size of 12 per H&Y group (3 groups of H&Y) should be adequate to provide means and variance for planning of future studies.

We also expect to enroll 1 caregiver for each participant enrolled.

We proposed up to 90 participants because we included persons who signed the consent but were ineligible to participate and those that started the protocol but dropped out.

4. * **List the study inclusion criteria:**
Parkinson's Participant
1) age 21 years or older,
2) PD confirmed by a movement disorder specialist using UK Brain Bank Criteria,
3) H&Y stage II, III, IV, or V.

Caregiver participant
1) Willing to complete questionnaire

5. * **List the study exclusion criteria:**
Parkinson's Participant
1) neurological, musculoskeletal, or other disorders unrelated to PD contributing to impairment of gait, stance, balance or coordination,
2) history of implantable cardiac device or ablative surgery,
3) moderate to severe cognitive impairment / dementia (Montreal Cognitive Assessment < 17/30), impairing the ability to follow simple commands during assessments and intervention sessions,
4) uncontrolled orthostatic hypotension,
5) feeding tube or associated port placement (PEG/J-PEG),
6) body height less than 5–1– or greater than 6–3– and
7) body weight greater than 250 pounds.

Caregiver participant
1) Unwilling to complete questionnaire

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
- ○ Included
- ● **Excluded - safety concerns if participants are unable to communicate with the study team**
- ○ Excluded - instruments/measures only validated in English
- ○ Excluded - no prospect of direct benefit to individual participants
- ○ Excluded - minimal risk study
- ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ○ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
Due to the ongoing COVID-19 pandemic we have experienced difficulties in recruiting individuals with late stage Parkinson's disease. We intend to continue in our attempts to recruit H&Y Stage V subjects; however, we are understanding of the personal decision to minimize exposure risk and decline participation in the study. The potential benefit of the device could also be extended to early disease staging, such as H&Y Stage II subjects. Potential subjects with Parkinson's disease are reporting greater inactivity due to changes in access to exercise-related services. We propose the inclusion of H&Y Stage II subjects to provide otherwise unavailable exercise-related intervention with documented medical benefit in this population.

For participants exhibiting moderate to severe cognitive impairment may still participant if scoring < 17/30 on the Montreal Cognitive Assessment if a legally authorized representative (LAR) approves participation. The subject must be able to follow commands associated with the listed outcome measures and follow instructions during walking intervention.

ID: MS4_HM20020066 View: SF2 - Background, Rationale & Goals Section Complete

Background, Rationale & Goals Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
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? POPULATIONS WITH SPECIAL CONSIDERATIONS
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Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Study Procedures

Study Procedures

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3. * **Choose all types of recruitment materials that may be used and upload them below:**
- [ ] E-mail invitations
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [ ] TelegRAM announcements
- [ ] Website text
- [ ] Study-specific web sites (provide the design and text)
- [ ] Social Media
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] Psychology Research Participant Pool (SONA) study descriptions
- [x] **Scripts for announcements made to groups**
- [ ] Other recruitment material
- [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address the following three aspects of recruitment in your response.**

1. Identification of potentially eligible participants or secondary data/specimens of interest.
- What database(s) will be queried to identify secondary data/specimens
- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
RECRUITMENT PROCESS:

HOW WILL POTENTIAL PARTICIPANTS BE IDENTIFIED AND THEIR CONTACT INFORMATION OBTAINED?
WHAT AND HOW WRITTEN OR VERBAL RECRUITMENT MATERIALS BE USED?

1) Screening during clinic visits (or in advance of clinic visits) at the Parkinson's Movement Disorder Center will be

accomplished by screening clinic schedules and looking at the Cerner electronic medical records to confirm patient's Parkinson's disease (PD) diagnosis.
This will be conducted by study staff. Patients with PD related gait disturbances will be informed of the study by their provider. If interested, they will be put in touch with the study staff directly or handed a post-card/flier described in #2.
2) Post-card/flier announcements will be available for review in clinic exam rooms. If the patient is interested, they can contact the study staff using the contact information on the card.
3) Post-card/flier announcements of the study will also be made available to local support groups and at local PD community events. If the patient is interested, they can contact the study staff using the contact information on the card.
4) The PMDC Research registry for PD patients interested in being contacted about research opportunities will be screened by the study coordinator.
5) The organizers of local support groups will be contacted and asked if they would be willing to allow study staff to speak to the groups. If allowed, study staff will inform the groups of the study (using the scripts for announcements made to groups). Post-card/flier announcements will be left with the groups and members can contact the study staff if interested.

Caregivers will be recruited after the PD participant has agreed to participate and is found to be eligible to participate in the study.

NOTE - A POST-CARD/FLIER WILL BE UPLOADED AFTER IRB APPROVAL WITH AN AMENDMENT.

All prospective participants will be called (i.e., identified by provider or from registry), or they will call the study coordinator (using information on post-card/flier). The study coordinator will inform them of the study and then ask if they are willing to participate. If yes, they will be asked the screening questions (see pre-screen phone script in documents). Pre-screen phone scripts will be destroyed immediately after determining eligibility. If they are eligible to participate and agreeable, they will be scheduled for an initial visit when the full consent will be explained, questions answered, and consent signed. Participants will receive a signed copy of the consent at that time. Participants will be verbally reminded (by phone or in person) when their next visit will occur.

If they do not meet the eligibility criteria, their name will be kept with a generic "did not meet eligibility criteria" so as not to be contacted again for the same study.

TIMING AND FREQUENCY OF RECRUITMENT ACTIVITIES

Recruitment will start once IRB approval is established. Frequency of recruitment activities will occur when patients are attending the PMDC clinic on a weekly basis. Support groups meet at most, monthly.

WHERE AND HOW RECRUITMENT PROCEDURES WILL BE COMPLETED

Recruitment will occur at the VCU Parkinson's and Movement Disorder Clinic on the 4th floor of the NOW building at Short Pump. Study staff will be available on clinic days to speak with potential participants identified by the patient's provider as interested in learning more about the study.

WHO WILL RECRUIT OR RESPOND TO POTENTIAL PARTICIPANTS?

The study coordinator and PIs will respond to potential participants.

ALL screening procedures described above are performed for the purpose of screening, recruiting or determining the eligibility of prospective subjects for this study.

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

   ○ Yes

   ● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   1. A statement explaining the study design
   2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
   3. A description of all research measures/tests/interventions that will be used (if applicable)

   See the help text for additional guidance
   PD Participants:
   3 hours are required for each the pre-, post-, and durability assessments in order to collect outcome measures, a 10 meter WT, a 6MWT, the BBS, disease severity with the Examination, part III of the UPDRS, and PDQ39. For visually impaired, either the caregiver or a member of the research staff will read the PDQ39 to the participant then answers will be documented. Additionally, the pre-assessment visit will also include consent review, the MoCA (or blind MoCA which will be given to visually impaired participants that may not be able to see what's on paper but are still able to see enough to walk) and medical history including height, weight and BP and an additional 6MWT with the device on to allow the patient to get familiar with the device prior to treatment. Safety will be ensured through use of a gait belt and two supervising staff providing lateral support as necessary. A harness system has been considered as it could potentially influence movement patterns and/or incite anxiousness, both of which have been observed when using body weight-supported systems in patients with PD. Two spotters will provide necessary anterior or posterior assistance in the case of a loss of balance. If a subject is unable to ambulate one length of the measured 6MWT (10 meters) while wearing the exoskeleton without physical assistance, a harness may be used during the training intervention. Post-intervention assessments will be completed within 1 week of the final study visit. Durability assessments will be completed between 4-6 weeks following the final study visit. All assessments and testing will be restricted to the patient's best on time.

   Subjects will participate in a total of 10 sessions, twice per week for 5 weeks, with the Keeogo® device and the APDM Mobility Lab wearable sensor system. (The APDM Mobility Lab wearable sensor system is an FDA approved device that measures to best track proficiency of exoskeleton device use and net effect on FOG: cadence, gait cycle duration, gait speed, double support time, stance time, step duration, stride length, swing phase, toe out angle, stride length variability, arm swing velocity, arm swing range of motion, and anticipatory postural adjustment via APA duration, first step duration, and first step range of motion. These anticipatory postural adjustment measures are specific to initiation of gait, a critical event impacted by FOG. Additionally, measures of truncal sway will further strengthen our assessment

of postural stability relative to dynamic walking.) A goal of 30 minutes total walking time is desired within each session. Participants will be able to rest, as needed. Completing 30 minutes of walking may require multiple walking trials within sessions due to fatigue. If a subject is unable to complete 30 minutes of walking within an allotted one-hour session, the total walking time will be recorded. The first six minutes of walking with the Keeogo device will be completed per the instructions of the 6MWT, in order to longitudinally measure proficiency with the device. Use of an assistive device will be allowed, though not required. Subjects may opt to utilize a platform rolling walker, rolling walker, bilateral Lofstrand crutches or a unilateral device, such as a cane or Lofstrand crutch. Assistive device of choice will be consistent with baseline and maintained throughout the intervention. Patients who are functionally non-ambulatory at baseline will utilize a rolling walker or platform rolling walker with the exoskeleton. One-hour sessions will allow for safety with setup and management of the exoskeleton. There are no restrictions or specific instructions necessary to users during the remainder of the session beyond the first six minutes of walking each session.

Caregiver:
The caregiver will be asked to complete the PD-Carer survey 3 times, once each at the PD participants pre-, post-, and durability assessments. They will be allowed to complete the survey in a private space. No identifying information will be collected from the caregiver. They will be given the same generic code as the PD participant.

7. * **The IRB only reviews research activities, so indicate which of the study activities are:**

- Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
- Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
- Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
All procedures are performed exclusively for research purposes.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

ID: MS4_HM20020066 View: SF2 - Project Details

Project Details

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [ ] Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations
   - [ ] Deception (misleading participants through false or incomplete information)
   - [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
   - [ ] Placebos
   - [x] **Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations**
   - [ ] Washout Periods
   - [ ] Expanded Access - Treatment Use of an Investigational Product
   - [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
   - [ ] Specimen/biological sample collection
   - [ ] None of the Above

2. * **Select all of the following types of interactions that apply to this study (selections will branch):**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [ ] Active Internet data collection (i.e. using the internet to interact or intervene directly with research participants)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [x] **Audio / Video recording or photographing participants**
   - [x] **Observations**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior)
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **Select all types of recordings that will be made:**
   - [ ] Audio
   - [x] **Video**

- [x] **Photographs**

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
Photographs and video's of walking may be used for the purposes of education, presentation of findings, and future data analysis. Photographs and video will be taken only from the neck down in order to maintain privacy for the participant.

5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**
   - [x] **Individually Identifiable Health Information (PHI or RHI)**
   - [ ] Secondary data/specimens NOT from a research registry or repository
   - [x] **Information/specimens from a research registry or repository (Usage Protocol)**
   - [ ] Information/specimens originally collected for a previous research study
   - [ ] Publicly available information/specimens
   - [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
   - [ ] No secondary data/specimens will be used

ID: MS4_HM20020066 View: SF2 - Bio-Medical Device Details

Bio-Medical Device Details

1. * **Select the type of device :**
   - [x] **Marketed Device (including 510k device) used as indicated**
   - [ ] Marketed but new indication or intended use
   - [ ] Mobile application or software function with regulatory discretion
   - [ ] Mobile application or software function without regulatory discretion
   - [ ] Investigational device
   - [ ] Humanitarian Use Device (HUD)

2. * **List devices this study will involve:**

Device	Manufacturer	Device Risk	IDE	IDE Holder
Keeogo Dermoskeleton	b-temia Inc.	Not Designated / Not Required	IDE Exempt	VCU Sponsor-Investigator
APDM Mobility Lab wearable sensor system	ERT	Not Designated / Not Required	n/a	Not Required

3. * **Describe how the device will be stored and controlled.**
The devices will be stored in its lock-bearing case, in a locked closet at NOW.

4. A. For each device listed above, **upload documentation of the approved use(s) (operation manual, instructions for use, etc.) or a detailed description of the design, use, and risks of the device.**

B1. If 'Investigational Medical Device' or 'New Use for Marketed Medical Device' was selected above AND the device qualifies for IDE exemption under under 21 CFR 812.2(c), upload one of the following documents for each applicable device:
- A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c).
- External sponsor's protocol including IDE exemption information
- Communication from the external sponsor verifying the IDE exemption
- Communication from the FDA with verification of IDE exemption

B2. Upload at least one of the following documents for each Significant Risk medical device:
- External sponsor's protocol including IDE number
- Communication from the external sponsor verifying the IDE number
- VCU sponsor-investigator's FDA IDE protocol including IDE number
- Communication from the FDA with verification of the IDE number

B3. Upload at least one of the following documents for each Non-Significant Risk medical device:
- External sponsor's protocol including a justification regarding the risk of the device (significant vs. non-significant)
- Communication from the sponsor holding the IDE, which provides a justification regarding the risk of the device (significant vs. non-significant) according to 21 CFR 812.3(m).

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent_exoskeleton	Consent_exoskeleton_01202022a.pdf	0.17	1/26/2022 2:55 PM	Mark Baron	Consent/Assent/Information Sheet	Yes
View	Consent_exoskeleton_large_print	Consent_exoskeleton_large_print_version_01202022.pdf	0.05	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent_SO	Consent_exoskeleton_SO_v1.1.pdf	0.08	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes
View	PROC not activated	PROC neurology not activated.pdf	0.01	1/20/2022 11:45 AM	GinaMari Blackwell	Ancillary Committee Approval	Not Applicable
View	VCU Informed Consent Evaluation Tool	ICEval.doc	0.01	2/23/2021 3:13 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Not Applicable
View	MoCA - blind	MoCA-Test-BLIND - 04-2020.pdf	0.01	2/1/2021 3:52 PM	GinaMari Blackwell	Research Measure	Yes
View	NSR Device APDM	APDM CE 510k exempt.pdf	0.01	11/10/2020 3:18 PM	GinaMari Blackwell	Other	Not Applicable
View	APDM User Manual	APDM MobilityLab_UserGuide.pdf	0.01	10/25/2020 5:14 PM	GinaMari Blackwell	Other	Not Applicable
View	Keeogo User Manual	IFU-006-EN v1.1 Keeogo_ User Manual (USA)_approved.pdf	0.02	10/14/2020 5:49 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	User Manual	IFU-003-EN v1.2_Keeogo_ Clinician Manual_approved.pdf	0.02	10/14/2020 5:48 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	Article for NSR device	Keeogo in MS open label.pdf	0.01	9/23/2020 10:49 AM	GinaMari Blackwell	Other	Not Applicable
View	Pre-screen phone script	prescreen phone script_exoskeleton2.docx	0.02	9/21/2020 3:59 PM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Consent from HM14555	PMDC registry-May 2019-clean.pdf	0.01	9/16/2020 11:09 AM	GinaMari Blackwell	Other	Not Applicable
View	Support Group Script	Script for Support Groups 9.16.20.docx	0.01	9/16/2020 10:42 AM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Demographics exoskeleton	Demographics exoskeleton.docx	0.01	8/17/2020 4:38 PM	Mark Baron	Research Measure	Yes
View	References	References.docx	0.01	8/13/2020 3:44 PM	GinaMari Blackwell	Other	Not Applicable
View	PDQ-Carer	FINAL_PDQ-C_English_UK.pdf	0.01	8/11/2020 1:12 PM	GinaMari Blackwell	Research Measure	Yes
View	MoCA	MoCA.pdf	0.01	8/10/2020 5:23 PM	GinaMari Blackwell	Research Measure	Yes
View	UPDRS-Part III	MDS-UPDRS_Part III.pdf	0.01	8/10/2020 5:20 PM	GinaMari Blackwell	Research Measure	Yes
View	PDQ-39	PDQ39.pdf	0.01	8/10/2020 5:02 PM	GinaMari Blackwell	Research Measure	Yes
View	Berg Balance Scale	BBS short form.pdf	0.01	8/10/2020 4:54 PM	GinaMari Blackwell	Research Measure	Yes
View	Hand Biosketch	Hand Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	No
View	Baron Biosketch	Baron Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	Yes
View	IDE Exemption	Keeogo_No IDE Req'd.pdf	0.01	8/10/2020 4:42 PM	GinaMari Blackwell	FDA Regulatory Document	Not Applicable

ID: MS4_HM20020066 View: SF2 - Secondary Data/Specimen Details

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
b. List what types of specimens will be obtained (when applicable); and/or
c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.

The VCU PMDC research registry is a database of individuals seen at the VCU Parkinson's and Movement Disorders Center who have already consented to be contacted about future research studies. The Data Registry includes information from routine clinical evaluations, including appropriate scales relevant to the clinical diagnosis, neurology examination and history notes, neuropsychology examination and history notes and cognitive and effective assessments, physical therapy examination and history notes and mobility ratings, speech therapy examination and history notes, and sleep specialty evaluations and examination and history notes.

This database will be screened by appropriate study staff to identify potential participants and call them on the phone to discuss the study.

The study staff will also screen the PMDC clinic schedule for potential participants. If a potential participant (someone with gait and balance problems) is found on the clinic schedule, the study staff will confirm their diagnosis in Cerner (the clinic's electronic medical record), and then notify the potential participant's provider. The provider will inform the potential participant about the study and provide them with the contact information of the study staff. The potential participant will be able contact the study staff. Any individual recruited in this manner will be fully consented, if they are interested in participating. Study staff will not keep any information about daily clinic schedules, they will only confirm whether the potential patient has a diagnosis of Parkinson's disease or not.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
Registry:
The identifiers that will be obtained are the names and contact information of prospective participants. This will be provided by the study staff member that is maintaining the PMDC registry of patients who have consented to be contacted for future research studies. We will not have to re-enter the PMDC registry for this study after recruitment efforts are complete. There are NO needs for code access to the registry. A separate coding system will be initiated specifically for this study and only persons who meet the eligibility criteria and agree to the initial screen will receive a code. Names of persons who are not interested or do not meet the eligibility criteria will kept in a separate spreadsheet that will be destroyed at the end of the recruitment period.

Clinic Patients and Cerner:
Once patients are identified by screening clinic schedules for people with gait and balance problems and confirmed Parkinson's diagnosis (via Cerner electronic medical records), the potential patient's healthcare provider will ask their patient if they would like to hear more about this study. The healthcare provider will give the patient the contact information for the study staff (post card). Study staff will not keep any information about daily clinic schedules or Cerner. There is no need to retain any information from Cerner.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - (●) **Yes**
   - ( ) No

4. * **Provide name(s) of the registry/repository being accessed.**
Parkinson's Disease Center Data Registry.

5. * **Site having responsibility for the management of this registry/repository:**
   - (●) **VCU**
   - ( ) Non-VCU

6. **If the registry / repository is located at VCU, provide the IRB number for the registry / repository.**
HM14555

7. * **Is the original consent form that participants signed upon entry into the registry /repository available?**
   - (●) **Yes**
   - ( ) No

8. **If YES, the original consent is available, upload it for the IRB to reference**

ID: MS4_HM20020066 View: SF2 - Costs to Participants

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [x] **Participants will have no costs associated with this study**
   - [ ] Study related procedures that would be done under standard of care
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices
   - [ ] Study drugs or devices
   - [ ] Other

ID: MS4_HM20020066 View: SF2 - Compensation

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's

guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**
   4. **how you arrived at this amount**

   Participants will not be compensated in this study.

2. **If compensation will be pro-rated, explain the payment schedule.**

3. * **Will Social Security Numbers be collected for compensation purposes only?**
   - ◯ Yes
   - ● **No**

ID: MS4_HM20020066 View: SF2 - Contingency Plan

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

ID: MS4_HM20020066 View: SF2 - Research Plan Complete

Research Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Consent Process

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Partial waiver for pre-screens from registry	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	Registry participants who appear to meet basic inclusion criteria will be contacted and offered participation in this study. Those interested will	Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of	Indefinite	

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							be scheduled for a study screening visit, at which time they will go through the informed consent process with study staff and will either choose to sign the form or not.	lie down (if they are able to) Other protection(s) not listed here describe below		
View	Clinic patients	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	If a potential participant is found in the clinic schedule and confirmation of diagnosis is confirmed by reviewing the patient's electronic medical records, the study staff will notify the potential participants provider. The provider will inform the potential participant about the study and provide them with the contact information of the study staff. The potential participant will be able contact the study staff.	Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to) Other protection(s) not listed here describe below	They will be allowed to take as much time as needed to read the ICF, ask questions, and make a decision. If they wish to take the informed consent form (ICF) home to think about it, they may do that and return at a later date to enroll in the study.	
View	Caregivers of PD Patient Participants	Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	Informed consent will be obtained at the start of the visit before any study procedures are done. The consent process will occur in a private exam room. After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but	Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to) Other protection(s) not listed here describe below	The caregiver will have until the first treatment visit of the PD patient to decide if they want to participate.	n/a

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							before they finish the study, they will be consented again with the most current consent form.			
View	Assent for Decisionally Impaired Adult	Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested	Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	Consent will be obtained from the Legally Authorized Representative of participants and assent will be obtained by the participant. Information about the study will be provided in oral and written form to the participants, prior to any study activities. Consent conversations will occur in a private room. Visually impaired participants will be given a large print version of the consent. After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but before they finish the study, they will be consented again with the most current consent form.	Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to) Other protection(s) not listed here describe below	Potential participants will be allowed to take as much time as they need to decide. They will be allowed to take the consent form home to review.	n/a
View	Potential PD Patient Participants	Signed Consent by Participant	No Waivers Requested	Principal Investigator Co/Sub-Investigator Research Coordinator Medical or Psychological Responsible Investigator		Not using electronic signature platforms	Informed consent will be obtained at the start of the visit before any study procedures are done. The consent process will occur in a private exam room. Visually impaired participants will be given a	Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to) Other	They will be allowed to take as much time as needed to read the ICF, ask questions, and make a decision. If they wish to take the informed consent form (ICF) home to	n/a

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						large print version of the consent. After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but before they finish the study, they will be consented again with the most current consent form.	protection(s) not listed here → describe below	think about it, they may do that and return at a later date to enroll in the study.	

2. Upload any consent / assent documents:

ID: MS4_HM20020066 View: SF2 - Waiver of Some or All Elements of Consent

Waiver of Some or All Elements of Consent

Consent groups that require a waiver of some or all elements of consent:

Group	Types	Waivers	Roles	Roles - Other	Consent	Decision	Status Change
Partial waiver for pre-screens from registry	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	Principal Investigator Co/Sub-Investigator Research Coordinator		Registry participants who appear to meet basic inclusion criteria will be contacted and offered participation in this study. Those interested will be scheduled for a study screening visit, at which time they will go through the informed consent process with study staff and will either choose to sign the form or not.	Indefinite	
Clinic patients	None of the Above (select waiver below)	Waiver of All Consent or Some Elements in Consent Form	Principal Investigator Co/Sub-Investigator Research Coordinator		If a potential participant is found in the clinic schedule and confirmation of diagnosis is confirmed by reviewing the patient's electronic medical records, the study staff will notify the potential participants provider. The provider will inform the potential participant about the study and provide them with the contact information of the study staff. The potential participant will be able contact the study staff.	They will be allowed to take as much time as needed to read the ICF, ask questions, and make a decision. If they wish to take the informed consent form (ICF) home to think about it, they may do that and return at a later date to enroll in the study.	

1. * **For each group listed at the top of this page, describe which elements of informed consent you are waiving or altering.**

- To request a waiver or alteration of SOME elements of informed consent, describe each of the elements that you wish to waive. See the help text for a list of elements, and copy/paste the descriptions of the elements (not just the element numbers) into this response.
- To waive ALL elements of informed consent, state "All elements of informed consent" in this response.
Individuals have previously provided written informed consent to be contacted about possible participation in other research studies. We are requesting a waiver of all elements of consent only to screen individuals in the registry and approach them for this study. Any individual recruited in this manner will be fully consented, if they are interested in participating.

We are also requesting a waiver of some of the elements of consent for individuals who are screened from the clinic schedule. If a potential participant is found in the clinic schedule, the study staff will confirm their diagnosis in Cerner (electronic medical record), and then notify the potential participant's provider. The provider will inform the potential participant about the study and provide them with the contact information of the study staff. The potential participant will be able contact the study staff. Any individual recruited in this manner will be fully consented, if they are interested in participating. Study staff will not keep any information about daily clinic schedules.

2. * **Will you be waiving parental permission for wards of the state (and/or a Legally Authorized Representative's consent) in any of the consent groups at the top of this page:**
   - ○ Yes
   - ● **No**

3. * **Is this study conducted by or subject to the approval of State or Local Government and designed to study, evaluate, or otherwise examine public benefit or service programs:**
   - ○ Yes
   - ● **No**

4. * **Explain how the research involves no more than minimal risk to the participants (Alternative question phrasing: How do the risk(s) of the research activity for which consent is being waived compare to the risks a person might reasonably experience in normal everyday life?)::**
   The "pre-screen from registry" waiver will allow us to contact people with Parkinson's disease who have already provided consent to be contacted about research studies.

   The "clinic schedule" partial waiver is no more than minimal risk because we are asking the potential participant's provider to speak to the patient first to reduce coercion. Study staff will not keep any information about daily clinic schedules.

5. * **Explain how the research could not practicably be carried out without the waiver or alteration (Alternative question phrasing: Why would obtaining consent from participants make the study not achievable or not viable?):**
   Our past experience has taught us that using our registry for recruitment, and screening clinic schedules (with confirmation of diagnosis via Cerner) and then asking providers to ask identified patients if they are interested in hearing more about the study are the most effective and expeditious ways to reach interested individuals.

   Confirming diagnosis via Cerner electronic medical records of potential patients screened from the clinic schedules is important so as to not falsely raise hope of participation in a study they do not qualify for, and not wasting patients time and cost of travel to the study site. This also improves efficiency of the research team.

6. * **Explain why this study can only be carried out using identifiable or de-identified information/biospecimens. - Studies with Department of Justice funding may state "Not applicable." (Alternative question phrasing: Why would it be impossible to conduct the study using only anonymous information/biospecimens?).**
   All direct and indirect identifying information that would enable the investigator to know the subject's identity will be removed or replaced with a number, letter, symbol, or combination thereof. Again, all video's will be scrubbed of identifiable images such as tattoo's and faces.

7. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants (Alternative question phrasing: Will this consent waiver violate any of the participant's rights or adversely affect their welfare - why or why not?):**
   The individuals from the registry have already provided consent to be contacted about research. Only their contact information and name will be shared with the staff of this study so that we may contact them.

   Individuals screened from weekly clinic schedules whose diagnosis was confirmed via their electronic medical record will be asked by their healthcare provider if they would like to hear more about the study. They can decline to speak with study staff or decline to participate in research without prejudice.

   Study staff will not keep any information about daily clinic schedules.

   Those interested will come in for a visit, where they will provide written informed consent for this protocol.

8. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not:**
   If either registry participants or screened clinic schedule participants (with diagnosis confirmed via electronic medical record by study staff) are interested, they will come in for a study visit where they will go through the full written informed consent process. Should any pertinent information arise after their participation has been completed, they will be contacted by phone or by mail with the relevant information updates.

ID: MS4_HM20020066 View: SF2 - Consent Plan Complete

Consent Plan Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**
   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   PD participant
   -loss of confidentiality and privacy,
   -skin irritation,
   -musculoskeletal injury,
   -falls,
   -fatigue,
   -episodes of symptomatic orthostasis, or
   -frustration with the intervention.

   Caregiver
   -loss of confidentiality and privacy,
   -some survey questions may make the participant uncomfortable.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   To minimize the risk of loss of confidentiality and privacy, data will be de-identified per protocol described in prior sections. Data on the computer will only be accessible on VCU's password protected computers and secure/encrypted databases.

   PD Participant
   During the first session a device fitting will occur to insure appropriate fitting and will be checked periodically to make sure device is still comfortable and not hurting the patient. The patient will wear a gait belt and someone will be walking the the patient at all times to prevent falls. Patients will be allowed to take additional breaks if necessary.

   Caregiver
   Participants will be allowed to skip questions.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   There are no potential risks or harms to a community or a specific population based on study findings.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   In the case of adverse event during device training, medical oversight is available by the team at NOW.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   If the patient gets injured, too frustrated, or the investigator determines that it is unsafe for the patient to continue, the investigator will withdraw the patient from the study.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   None

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**
   - ☐ DSMB
   - ☑ **DSMP**
   - ☐ No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe your Data Safety Monitoring Plan for monitoring the study's data to ensure the safety of participants. This plan should include (but is not limited to) the following elements:**
   1. Who will monitor data
   2. What data and/or processes will be reviewed
   3. When and how frequently monitoring will occur
   4. What report/documentation will be submitted to the IRB at the time of continuing reviews

   See the help text for additional guidance.

   An independent study monitor will oversee the conduct of the trial in order to assure that all staff members are adhering to the protocol, standard operating procedures, tenets of good clinical practice, and all local and federal research regulations.

   Our strict adherence to the inclusion and exclusion criteria, and also to the other aspects of the protocol will help ensure participant safety. Dr. Baron will provide medical oversight to assess and grade all adverse events. He will refer as needed to appropriate medical providers to manage any adverse events that may occur.

   Monitoring will occur after 25% of participants complete the study. Monitoring will occur again after 50%, 75% and 100% participants complete the study.

   The study PI will report adverse events to the IRB as appropriate and per VCU IRB policy.

   At the time of continuing review, the IRB will receive a report containing enrollment data, patient safety data, adverse event summaries.

ID: MS4_HM20020066 View: SF2 - Privacy

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. Not all will be applicable to every study.

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [x] **Asking the participant if they are comfortable answering questions in that location**
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**
   - [x] **Moving away from other people when conducting activities in public spaces or offering a private space**
   - [x] **Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding**
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [x] **Other protections not listed in this question – describe below**
   - [ ] N/A – study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session

- [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
- [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
- [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
- [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
- [ ] Allowing people to distance themselves from other participants during group activities
- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question ' describe below
- [x] **N/A ' study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**

- [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**
- [x] **Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.**
- [x] **Obtaining permission prior to sending text messages**
- [x] **Advising the participant to move to a location where they are comfortable answering questions and will not be overheard**
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [x] **Offering a way to save and return later to the online activity if privacy is compromised**
- [ ] Other protections not listed in this question ' describe below
- [ ] N/A ' study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**

- [x] **Obtaining permission to mail study materials**
- [x] **Confirming/verifying the accuracy of addresses before mailing items**
- [x] **Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)**
- [x] **Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.**
- [x] **Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)**
- [x] **Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address**
- [x] **Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer**
- [x] **Offering other options of ways to complete the activity (i.e. by phone or online) if desired**
- [ ] Other protections not listed in this question ' describe below
- [ ] N/A ' not mailing any materials to/from participants

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:

- [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
- [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
- [x] **Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform**
- [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
- [x] **Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing**
- [ ] Only publishing or presenting aggregate results or findings (i.e. no individual-level information)
- [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images ' describe below
- [ ] Other protections not listed in this question ' describe below

6. **Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance.***
Potential participants will be recruited out of our clinic at the Parkinson's and Movement Disorders Clinic, physical therapy patients or support groups. Most of the participants will already be patients.

Potential participants will be informed that their decision to participate in this study will have no impact on their clinical care. The informed consent process will occur in a private room where the individual will be able to ask questions.

Study procedures will be conducted at the VCUHealth Neuroscience, Orthopaedics and Wellness Center in the physical therapy gym space. Study procedures that are confidential in nature will occur in a private setting.

No PHI will be attached to the data when it is published/disseminated.

ID: MS4_HM20020066 View: SF2 - Data Confidentiality and Storage

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
   - [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
   - [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
   - [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [x] **Other protection not listed in this question – describe below**
   - [ ] N/A – no paper research materials

2. * **Protections for research specimens:**
   - [ ] Maintaining control of specimens at all times, including when at an off-campus location
   - [ ] Storing specimens in a secure location accessible only to authorized study personnel
   - [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
   - [ ] Final destruction of specimens will be devoid of any identifiable information
   - [ ] Other protection not listed in this question – describe below
   - [x] **N/A – no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
   - [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
   - [x] **When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps):**
     – consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/);
     – advising participants about the terms of use and privacy policies of those sites/apps;
     – limiting or avoiding use of identifiers; and
     – removing data promptly from the external location after transferring it to a VCU storage location
   - [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
   - [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - [x] **When analyzing particularly sensitive information, using computers that are unconnected from the internet.**

- [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
- [ ] Other protection not listed in this question – describe below

4. * **Protections for computers and research devices/apps that are provided to participants for use in the study:**

- [ ] Transferring data promptly from the device/app to a VCU storage location
- [ ] Setting strong passwords on computers and research devices (when applicable)
- [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
- [ ] Other protection not listed in this question – describe below
- [x] **N/A – no computers or devices/apps being provided for participant use**

5. * **Protections for email/online communications**

- [x] **Only using VCU/VCU Health email addresses for study-related communications**
- [x] **Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
- [ ] Other protection not listed in this question – describe below
- [ ] N/A – no email/online communications

6. Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.

See the help text for additional guidance.
Upon enrollment, subjects shall be assigned a study identification number. This number will be used to identify all of their paper and electronic data on the Case Report Forms (CRFs). The key that matches participants PHI to their study number will be stored in a separate locked cabinet from the data and accessible only to the investigators.

We will utilize a combination of electronic and paper CRFs. Paper CRFs will be stored in a locked cabinet in a locked office within the research suite at NOW. Upon completion of the study, the paper CRFs will be stored in the locked file cabinets in a locked office until they can be destroyed as allowed by the FDA and IRB. Electronic CRFs will be completed using REDCap.

7. * **If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team or the PI's department, identify the data recipient(s) along with their VCU department or other institutional or organizational affiliation(s).**
Any data that is shared with groups/persons outside VCU will not contain any HIPAA identifiers.

8. * **Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**

- [x] **Names**
- [ ] Geographic Locators Below State Level
- [ ] Social Security Numbers
- [x] **Dates (year alone is not an identifier)**
- [x] **Ages over 89 (age under 89 is not an identifier)**
- [x] **Phone Numbers**
- [ ] Facsimile Numbers
- [x] **E-mail Addresses**
- [x] **Medical Record Numbers**
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names with assigned subject IDs, explain the following aspects of the coding process:**

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)
- Whether there will be a key that links the subject ID with direct identifiers.

If a key will be created, describe
- The place where the key will be stored
- The role(s) of all individuals who will have access to the key
- When the key will be destroyed

See the help text for guidance.
1. Sequential numbers
2. A key that matches number to name, DOB, MRN, and contact information will be made
3. The key will be kept in a separate location from the CRFs in a locked cabinet inside a locked office in the research suite at the NOW building
4. Only Gina Blackwell and Dr. Robert Hand will have access
5. Key will be destroyed when final data analysis is complete
6. Before any future research use or share of the research data generated under this study, all identifiers will be removed from all research data generated under this study (paper and electronic) and all key code will be destroyed so that no one (not even the VCU study team) can re-identify subjects from the remaining research data.

ID: MS4_HM20020066 View: SF2 - Data Retention

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - ☐ Immediately destroy the information and identifiers (no data collected)
   - ☐ Immediately destroy the identifiers connected with the data (anonymization)
   - ☑ **Store until the end of study & then destroy**
   - ☑ **Use as "screening failure" data by members of the study team**
   - ☐ Provide to others outside of the research team (with the participant's permission)
   - ☐ Request permission from participant to maintain and use the identifiable information
   - ☐ Other
   - ☐ N/A - study does not require screening procedures
2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No - see help text)**
   - ○ Yes
   - ● **No**
3. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - ● **Stored indefinitely with identifiers removed**
   - ○ Stored indefinitely with identifiers attached
   - ○ Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
   - ○ Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ○ Other
4. * **Will audio/video recordings and full face photographs be destroyed?**
   - ○ Yes
   - ● **No**
5. **If yes, describe at what point and how recordings will be destroyed:**
6. **If no, explain why the recordings need to be maintained:**
   Full-face videos and photographs will not be recorded. The below the neck videos and photographs will be stored on VCU's encrypted server.

ID: MS4_HM20020066 View: SF2 - Sharing Plan

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   ○ Yes
   ● **No**

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ○ Yes ● **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   ● **No - Will not obtain CoC for this study**
   ○ Yes - CoC has been obtained or issued automatically
   ○ Yes - CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (i.e. analyses beyond/apart from the aims of this study)?** ***See help text for definitions.***

   ☐ Will use directly identifiable information or specimens.

   ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)

   ☐ Will use de-identified or indirectly identifiable information or specimens.

   ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. You will be asked more questions about this on a later page)

   ☑ Will use anonymized information or specimens.

   ('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)

   ☑ Will use aggregate results (summary-level results), not individual-level information or specimens.

   (The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)

   ☐ Will contribute to an existing registry or repository

   (You will be asked more questions about this on a later page.)

   ☐ Will not use information/specimens for purposes beyond this study.
   ☐ Not sure and will submit an amendment when known
   ☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).** ***See help text for definitions.***

   ☐ Will share directly identifiable information or specimens with other researchers.

('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. You will be asked more questions about this on a later page.)

☐ Will share de-identified or indirectly identifiable information or specimens with other researchers.

('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. You will be asked more questions about this on a later page.)

☑ Will share anonymized information or specimens with other researchers.

('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)

☑ Will only share aggregate results (summary-level results), not individual-level information or specimens.

(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)

☐ Will contribute to an existing registry or repository (You will be asked more questions about this on a later page.)

☐ Will submit data to an NIH genomic data repository (You will be asked more questions about this on a later page.)

☐ Will not share information/specimens with other researchers.

☐ Not sure and will submit an amendment when known

☐ Other sharing of individual-level information with other researchers

6. * **Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)**

☑ **The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)**

☐ The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.

☐ The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.

☐ Other reason why anonymous use/sharing is not inconsistent with the consent document

7. * **The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:**

- all 18 HIPAA identifiers (including all dates) will be removed;
- all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
- a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
- the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

See help text for more information.

● **Yes**

○ No

8. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

● **Yes**

○ No

○ N/A - No sharing will occur

ID: MS4_HM20020066 View: SF2 - Pertinent Results and Incidental Findings

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**

○ Yes

● **No**

ID: MS4_HM20020066 View: SF2 - Risk Benefit Complete

Risk Benefit Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Populations with Special Considerations

Populations with Special Considerations

1. * **Check all participant groups that will be either**

a) Specifically included in this study or

b) Discernable in the research data/specimens.

(Selections will branch)

- ☐ Children
- ☐ Emancipated minors
- ☐ Wards of the State
- ☐ Pregnant women or fetuses
- ☐ Neonates or Post-delivery Materials
- ☐ Prisoners
- ☑ **Decisionally Impaired Adults**
- ☐ VCU / VCUHS students or trainees
- ☑ **VCU / VCU Health System employees**
- ☐ Individuals with limited English proficiency
- ☐ Active military personnel
- ☐ Student populations in K-12 educational settings or other learning environments
- ☐ Members of a federally recognized American Indian and Alaska Native tribe
- ☐ None of the Above

2. **Additional considerations for VCU/VCU Health System employees:**

* **Describe how the study will minimize the possibility of coercion to participate.**
We will not directly solicit employees. However, if someone we encounter in clinic or via the registry or is a caregiver of a participant that happens to work for VCU, we will not exclude them on this basis.

Subjects exhibiting moderate to severe cognitive impairment may still participant if scoring < 17/30 on the Montreal Cognitive Assessment if a legally authorized representative (LAR) approves participation. The subject must be able to

follow commands associated with the listed outcome measures and follow instructions during walking intervention.

ID: MS4_HM20020066 View: SF2 - Decisionally Impaired Adults

Decisionally Impaired Adults

1. * **Choose the nature of the decisional impairment participants will have:**
   - ○ Temporarily Incompetent to Give Consent
   - ● **Permanently Incompetent to Give Consent**
   - ○ Unknown

2. * **Explain why this population is necessary for the conduct of the study.**
   Parkinson's disease is a neurodegenerative disease that can cause dementia. The further a persons progression of the disease, the more likely they are to develop dementia. Since the study is enrolling persons with advanced PD (H&Y 4 & 5) we anticipate that some of our patients will have dementia.

3. * **Describe methods for determining whether participants are capable of providing consent or assent.**
   Most of the participants that will be in the study are clinically familiar with the investigator. The investigator and study coordinator will determine if a participant is competent to provide consent during the consenting process. If an individual is able to explain the study and the required involvement upon questioning, they will be deemed competent. We will use the VCU Informed Consent Evaluation Tool to verify the individuals ability to explain the study.

4. * **If a participant is capable of exercising some judgment concerning the nature of the study, describe how assent will be obtained.**
   Decisionally impaired adults will be given the opportunity to provide assent. The research study will be explained in basic terms and each individual will be asked whether or not he/she wishes to participate in research, particularly if he/she can comprehend and appreciate what it means to be a volunteer.

5. **Describe, if applicable, how the individuals' ability to give consent will be assessed throughout the study and how consent will be obtained when appropriate.**
   There are multiple visits over the course of up to 14 weeks. We do not expect an individuals ability to consent to change in such a short period of time. After each study visit, the study team will verbally ask the individual if they can briefly explain what is expected of them at the next study visit and if they are willing to continue.

6. * **Describe how and when consent will be obtained from participants' legally authorized representative (LAR).**
   Consent will be obtained from legally authorized representative (LAR) when an adult is not capable of providing informed consent. Consent will be obtained at the beginning of the initial visit before any research activity occurs. LARs will be expected to be at every visit since they will most likely also be the participants caregiver and transportation. Since they will be at visits, they can also confirm participants the continued participation.

ID: MS4_HM20020066 View: SF2 - Populations with Special Considerations Section Complete

Populations with Special Considerations Section Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Study Funding

Study Funding

1. * **Have you applied for funding:**
   - ● **Yes**
   - ○ No

2. **Is this study already funded:**
   - ● **Yes**
   - ○ No

3. * **Select all funding sources for this study (pending or awarded):**
   - ☐ Industry

- [ ] Direct Federal
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Non-Profit - Sponsored Project
- [ ] Non-Profit - Gift
- [x] **Internal Grant**
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

4. Select all related funding proposals that have been submitted through the Office of Sponsored Programs (OSP):

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End
There are no items to display						

ID: MS4_HM20020066 View: SF2 - Types of Sites

Types of Sites

VCU Site Information

1. * Select all VCU sites that will be utilized in this study:

- [ ] Children's Hospital of Richmond at VCU
- [ ] Clinical Research Services Unit (CRSU)
- [ ] Massey Cancer Center
- [ ] VCU Health Community Memorial Hospital
- [ ] VCU Health Tappahannock Hospital
- [ ] VCU Medical Center
- [ ] Other VCU Health Location
- [ ] VCU Monroe Park Campus
- [ ] VCU Qatar
- [x] **Other VCU Site**

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply:
a) Non-VCU sites that will be collaborating on a VCU-led study
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * Select any of the following non-VCU sites utilized in this study:

- [ ] McGuire VAMC
- [ ] Foreign Sites
- [ ] Other Non-VCU Sites
- [x] **No Non-VCU Sites**

3. * Is this a multi-center study being led by VCU?

○ Yes ● **No**

4. For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:

- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent_exoskeleton	Consent_exoskeleton_01202022a.pdf	0.17	1/26/2022 2:55 PM	Mark Baron	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent_exoskeleton_large_print	Consent_exoskeleton_large_print_version_01202022.pdf	0.05	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes
View	Consent_SO	Consent_exoskeleton_SO_v1.1.pdf	0.08	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes
View	PROC not activated	PROC neurology not activated.pdf	0.01	1/20/2022 11:45 AM	GinaMari Blackwell	Ancillary Committee Approval	Not Applicable
View	VCU Informed Consent Evaluation Tool	ICEval.doc	0.01	2/23/2021 3:13 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Not Applicable
View	MoCA - blind	MoCA-Test-BLIND - 04-2020.pdf	0.01	2/1/2021 3:52 PM	GinaMari Blackwell	Research Measure	Yes
View	NSR Device APDM	APDM CE 510k exempt.pdf	0.01	11/10/2020 3:18 PM	GinaMari Blackwell	Other	Not Applicable
View	APDM User Manual	APDM MobilityLab_UserGuide.pdf	0.01	10/25/2020 5:14 PM	GinaMari Blackwell	Other	Not Applicable
View	Keeogo User Manual	IFU-006-EN v1.1 Keeogo_ User Manual (USA)_approved.pdf	0.02	10/14/2020 5:49 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	User Manual	IFU-003-EN v1.2_Keeogo_ Clinician Manual_approved.pdf	0.02	10/14/2020 5:48 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	Article for NSR device	Keeogo in MS open label.pdf	0.01	9/23/2020 10:49 AM	GinaMari Blackwell	Other	Not Applicable
View	Pre-screen phone script	prescreen phone script_exoskeleton2.docx	0.02	9/21/2020 3:59 PM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Consent from HM14555	PMDC registry-May 2019-clean.pdf	0.01	9/16/2020 11:09 AM	GinaMari Blackwell	Other	Not Applicable
View	Support Group Script	Script for Support Groups 9.16.20.docx	0.01	9/16/2020 10:42 AM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Demographics exoskeleton	Demographics exoskeleton.docx	0.01	8/17/2020 4:38 PM	Mark Baron	Research Measure	Yes
View	References	References.docx	0.01	8/13/2020 3:44 PM	GinaMari Blackwell	Other	Not Applicable
View	PDQ-Carer	FINAL_PDQ-C_English_UK.pdf	0.01	8/11/2020 1:12 PM	GinaMari Blackwell	Research Measure	Yes
View	MoCA	MoCA.pdf	0.01	8/10/2020 5:23 PM	GinaMari Blackwell	Research Measure	Yes
View	UPDRS-Part III	MDS-UPDRS_Part III.pdf	0.01	8/10/2020 5:20 PM	GinaMari Blackwell	Research Measure	Yes
View	PDQ-39	PDQ39.pdf	0.01	8/10/2020 5:02 PM	GinaMari Blackwell	Research Measure	Yes
View	Berg Balance Scale	BBS short form.pdf	0.01	8/10/2020 4:54 PM	GinaMari Blackwell	Research Measure	Yes
View	Hand Biosketch	Hand Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	No
View	Baron Biosketch	Baron Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	Yes
View	IDE Exemption	Keeogo_No IDE Req'd.pdf	0.01	8/10/2020 4:42 PM	GinaMari Blackwell	FDA Regulatory Document	Not Applicable

ID: MS4_HM20020066 View: SF2 - Personnel

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:
- Conflict of interest investigators, including
- the PI
- the Lead Student/Trainee Investigator,
- medically/Psychologically responsible investigator(s)
- FDA Form 1572 investigators, and
- Other personnel whose roles are essential to the conduct of the research.

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Mark Baron	Principal Investigator Medical or Psychological Responsible Investigator		Data Collection - Direct Observation Participant Consent Data Collection - Lab Data Collection - Clinical Participant Identification Study Design Participant Recruitment Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	GinaMari Blackwell	Other	Study Coordinator	Project Coordination Participant Consent Regulatory Management Data Management Participant Identification Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Education and/or Professional Preparation		no
View	Ronald Elswick	Other	Biostatistician	Data Analysis Data Management Study Design		Education and/or Professional Preparation		no

2. Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above,**describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
The staff of the Parkinson's and Movement Disorders Center engaged in this research work very closely in their respective roles. They communicate about clinical and research related topics and issues at scheduled weekly meetings. Prior to participating, all engaged personnel will participate in a meeting to review the protocol. Special meetings will be held as necessary to update all staff on any changes to the protocol.

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

ID: MS4_HM20020066 View: SF2 - Conflict of Interest

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
◯ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
Non-financial Interests could include such things as:
- utilizing your unlicensed intellectual property in the study,
- serving as an unpaid advisory board member or officer/director with a related entity, and
- equity or business ownership in a company that has yet to make a profit and is related to this project
- conflict of time/effort,
- personal and professional relationships/affiliations,
- intellectual passions or personal beliefs
- other factors that could create bias in the study
◯ Yes ● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.
none

ID: MS4_HM20020066 View: SF2 - Other VCU Requirementsv2

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. **Cost Coverage Analysis**
Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

    1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
    ● **Yes**
    ◯ No
    ◯ Not Applicable

2. **ClinicalTrials.gov Program & OnCore**
For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

    1. * **Is this a Clinical Trial?**
    ● **Yes** ◯ No

    2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

    - Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
    - When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
    - When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).
    ● **Yes** ◯ No

3. **Community Engagement**
For more information, see https://community.vcu.edu/

    1. * **Is this a community engaged research study? (See help text for definitions)**
    ◯ Yes
    ● **No**

4. **Family Educational Rights and Privacy Act (FERPA) Requirements**
For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
   - ○ Yes
   - ● **No**

5. Research Data Privacy Requirements
Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB's oversight, obtaining data in, or from, a foreign country?**
   - ○ Yes ● **No**

6. Information Security
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

   Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**
   - ● **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   - ○ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**
   - ● **Yes**
   - ○ No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be created. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
   - ● **Yes** ○ No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):
   - ● **Yes** ○ No

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.massey.vcu.edu/research/protocol-review/

1. * **Does this study involve any of the following?**
   - Research involving patients with cancer, their families or their health care providers
   - Research involving cancer screening, diagnosis or prevention
   - Secondary data collected from cancer patients or their medical records
   - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population
   - ○ Yes
   - ● **No**

8. VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see https://onetrac.vcu.edu/

1. * **Does this study involve research with any of the following?**

   - VCU Health System patients

   - VCU Health System facilities

   - VCU Health System data
   - ○ Yes
   - ● **No**

9. VCU Health Department of Patient Centered Services

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**
   - ○ Yes
   - ● **No**
   - ○ Not Applicable

10. VCU Faculty-Held IND or IDE
For guidance, see **http://go.vcu.edu/indide**

1. * **The PI has reviewed and agreed to comply with the VCU policy "Reporting Sponsor-Investigator Investigational New Drug Applications (IND) or Investigational Device Exemptions (IDE).**
   - ● **Yes**
   - ○ No

11. VCU Health System locations

1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**
   - ● **Yes**
   - ○ No
2. * **The PI has reviewed and agreed to comply with the VCU Health System Research in Patient Care Areas policy (https://research.vcu.edu/compliance_program/vcuhs_policies.htm):**
   - ● **Yes**
   - ○ No

12. VCUHS Department of Pathology
Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
   - Storage of Microbiology isolates
   - New instrumentation provided by clinical trial/study sponsor, or
   - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)
   N/A - my study does not involve any of the listed processes.
2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**
   N/A - my study won't involve specimen retrieval from Pathology

13. VCU Institutional Biosafety Committee (IBC)
To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents (biohazardous agents) that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

   - Any functional recombinant viruses (especially viruses that may integrate into the patients genome).

   - Expression or administration of biological toxins.

   - Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

   - Introduction or expression of rDNA or synthetic nucleic acids

   - Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

   - Use of a product (purified growth factors, cytokines) produced from mammals or their cells.
   - ○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)
To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**
   - ○ Yes
   - ● **No**

15. VCU Scientific Review Committee (SRC)
For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**
   - ○ Yes
   - ● **No**

   Based upon your responses, this study will be routed to the VCU Scientific Review Committee (SRC) when it is submitted. After SRC review is completed, the IRB will receive the study.

16. Upload any documents requested in the questions above:

ID: MS4_HM20020066 View: SF2 - HIPAA

HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements
For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - ☑ **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - ☐ Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)
   - ☐ PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entity's health records

2. * **Summarize the types of health information that will be obtained or used in this research. Do not describe only the identifiers that you will collect or use during the study.**
   We will collect: name, DOB, contact information (phone and email), medical record numbers, and medical history related to PD diagnosis (date of Parkinson's diagnosis, medication list, medical history, gait impairments).

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
   Most information will be collected directly from patients. Outpatient records from neurology may be reviewed to confirm PD diagnosis during screening.

4. * **Does the PI certify that this study's access to and use of the protected health information is limited to the minimum amount necessary to be able to effectively conduct the research?**
   - ● **Yes** ○ No

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
   - ☐ De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
   - ☐ Limited Data Set
   - ☐ Waiver of Authorization
   - ☑ **Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)**
   - ☑ **Signed Authorization Combined with Consent Form**
   - ☐ Signed Authorization as Stand-Alone Form

ID: MS4_HM20020066 View: SF2 - Partial Waiver of Authorization

Partial Waiver of Authorization

1. * **Select the purpose for requesting the partial waiver of authorization:**
   - ☑ **Identify possible participants to recruit for the study**
   - ☐ Waive some elements of authorization (such as signature)

2. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:**
   (Alternative question phrasing: How do the risk(s) of this use of identifiable health information compare to the risks to privacy a person might reasonably experience in normal everyday life?).
   Partial waiver is for recruiting only. One method of recruitment will to review records in the PMDC registry to determine

which participants interested in being contacted for research opportunities also meet the basic inclusion/exclusion criteria for this study. Registry study staff will record only the basic contact information to transmit to our study staff to enable us to contact them, explain the study, and determine if they wish to be scheduled for a screening visit. Informed consent will be obtained at that screening visit prior to any further assessments.

3. * **If you selected "Identify possible participants to recruit" above, describe when will the 18 HIPAA identifiers be destroyed for those who do not eventually enroll in the study?**

- [ ] Following Participant Contact
- [x] **Upon Reaching Study Accrual Objectives**
- [ ] Other

4. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
No one.

5. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
(Alternative question phrasing: Why is this partial waiver necessary to make the study achievable or viable?)
Recruitment in prior studies at the VCU Parkinson's Movement Disorder Clinic (PMDC) has proven that targeting our registry and clinic populations is the most successful means of recruiting for clinical trials.

6. * **In applying for a partial waiver of authorization, the PI agrees to the following:**

A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law.

B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB/Privacy Board.

C) I will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above.

D) I assume responsibility for all uses and disclosures of the PHI by members of my study team.

- (●) **Yes**
- ( ) No

ID: MS4_HM20020066 View: SF2 - Institutional Requirements Complete

Institutional Requirements Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS
? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

Click Continue below to go to the next section

ID: MS4_HM20020066 View: SF2 - Documents

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
A list of potential documents is given in the help text.

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.

- A separate window will open that shows all versions of the document that have been added to RAMS-IRB.
Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent_exoskeleton	Consent_exoskeleton_01202022a.pdf	0.17	1/26/2022 2:55 PM	Mark Baron	Consent/Assent/Information Sheet	Yes
View	Consent_exoskeleton_large_print	Consent_exoskeleton_large_print_version_01202022.pdf	0.05	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes
View	Consent_SO	Consent_exoskeleton_SO_v1.1.pdf	0.08	1/26/2022 2:55 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Yes
View	PROC not activated	PROC neurology not activated.pdf	0.01	1/20/2022 11:45 AM	GinaMari Blackwell	Ancillary Committee Approval	Not Applicable
View	VCU Informed Consent Evaluation Tool	ICEval.doc	0.01	2/23/2021 3:13 PM	GinaMari Blackwell	Consent/Assent/Information Sheet	Not Applicable
View	MoCA - blind	MoCA-Test-BLIND - 04-2020.pdf	0.01	2/1/2021 3:52 PM	GinaMari Blackwell	Research Measure	Yes
View	NSR Device APDM	APDM CE 510k exempt.pdf	0.01	11/10/2020 3:18 PM	GinaMari Blackwell	Other	Not Applicable
View	APDM User Manual	APDM MobilityLab_UserGuide.pdf	0.01	10/25/2020 5:14 PM	GinaMari Blackwell	Other	Not Applicable
View	Keeogo User Manual	IFU-006-EN v1.1 Keeogo_ User Manual (USA)_approved.pdf	0.02	10/14/2020 5:49 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	User Manual	IFU-003-EN v1.2_Keeogo_ Clinician Manual_approved.pdf	0.02	10/14/2020 5:48 PM	GinaMari Blackwell	Drug/Device Brochure	Not Applicable
View	Article for NSR device	Keeogo in MS open label.pdf	0.01	9/23/2020 10:49 AM	GinaMari Blackwell	Other	Not Applicable
View	Pre-screen phone script	prescreen phone script_exoskeleton2.docx	0.02	9/21/2020 3:59 PM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Consent from HM14555	PMDC registry-May 2019-clean.pdf	0.01	9/16/2020 11:09 AM	GinaMari Blackwell	Other	Not Applicable
View	Support Group Script	Script for Support Groups 9.16.20.docx	0.01	9/16/2020 10:42 AM	GinaMari Blackwell	Recruitment/Advertising	Yes
View	Demographics exoskeleton	Demographics exoskeleton.docx	0.01	8/17/2020 4:38 PM	Mark Baron	Research Measure	Yes
View	References	References.docx	0.01	8/13/2020 3:44 PM	GinaMari Blackwell	Other	Not Applicable
View	PDQ-Carer	FINAL_PDQ-C_English_UK.pdf	0.01	8/11/2020 1:12 PM	GinaMari Blackwell	Research Measure	Yes
View	MoCA	MoCA.pdf	0.01	8/10/2020 5:23 PM	GinaMari Blackwell	Research Measure	Yes
View	UPDRS-Part III	MDS-UPDRS_Part III.pdf	0.01	8/10/2020 5:20 PM	GinaMari Blackwell	Research Measure	Yes
View	PDQ-39	PDQ39.pdf	0.01	8/10/2020 5:02 PM	GinaMari Blackwell	Research Measure	Yes
View	Berg Balance Scale	BBS short form.pdf	0.01	8/10/2020 4:54 PM	GinaMari Blackwell	Research Measure	Yes
View	Hand Biosketch	Hand Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	No
View	Baron Biosketch	Baron Biosketch.pdf	0.01	8/10/2020 4:51 PM	GinaMari Blackwell	CV/Biosketch	Yes
View	IDE Exemption	Keeogo_No IDE Req'd.pdf	0.01	8/10/2020 4:42 PM	GinaMari Blackwell	FDA Regulatory Document	Not Applicable

ID: MS4_HM20020066 View: SF2 - Documents Complete

Documents Complete

Protocol Progress:
? INITIAL SETUP
? BACKGROUND, RATIONALE & GOALS
? RESEARCH PLAN
? CONSENT PLAN
? RISKS, PRIVACY & CONFIDENTIALITY
? POPULATIONS WITH SPECIAL CONSIDERATIONS

? INSTITUTIONAL REQUIREMENTS
? DOCUMENTS

End of Application

Click Continue below to exit and submit this project

ID: MS4_HM20020066 View: Copy of Bio-Med Devices

Bio-Medical Devices

1. * **Name:**
   Keeogo Dermoskeleton
2. * **Manufacturer:**
   b-temia Inc.
3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Not Designated / Not Required
4. * **Indicate the device's IDE number if a protocol was submitted to the FDA for any investigational device or new use of a marketed device (regardless of what the FDA's determination was).**

   Or, if a protocol was not submitted to the FDA:
   - Enter "Abbreviated IDE" if the sponsor or sponsor-investigator has designated the device as a Non-Significant Risk device
   - Enter "IDE Exempt" if the sponsor or sponsor-investigator has determined that the device qualifies for IDE exemption
   - Enter "Regulatory Discretion" for a mobile application with regulatory discretion
   - Enter the FDA-provided HDE number if a HUD is being used in a clinical investigation for the HDE-approved indication(s).

   IDE Exempt
5. * **Select who holds the Investigational Device Exemption (FDA-granted IDE or Abbreviated IDE) for the device:**

   ○ External to VCU Sponsor or Investigator

   ● **VCU Sponsor-Investigator**

   ○ VCU Sponsor who is not the Investigator

   ○ Not Required
6. **If someone other than the PI is the sponsor for the IDE, name the entity or individual who will be the IDE sponsor.**

ID: MS4_HM20020066 View: Copy of Bio-Med Devices

Bio-Medical Devices

1. * **Name:**
   APDM Mobility Lab wearable sensor system
2. * **Manufacturer:**
   ERT
3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Not Designated / Not Required
4. * **Indicate the device's IDE number if a protocol was submitted to the FDA for any investigational device or new use of a marketed device (regardless of what the FDA's determination was).**

   Or, if a protocol was not submitted to the FDA:
   - Enter "Abbreviated IDE" if the sponsor or sponsor-investigator has designated the device as a Non-Significant Risk device
   - Enter "IDE Exempt" if the sponsor or sponsor-investigator has determined that the device qualifies for IDE exemption
   - Enter "Regulatory Discretion" for a mobile application with regulatory discretion
   - Enter the FDA-provided HDE number if a HUD is being used in a clinical investigation for the HDE-approved indication(s).

   n/a
5. * **Select who holds the Investigational Device Exemption (FDA-granted IDE or Abbreviated IDE) for the device:**

- ○ External to VCU Sponsor or Investigator
- ○ VCU Sponsor-Investigator
- ○ VCU Sponsor who is not the Investigator
- ● **Not Required**

6. **If someone other than the PI is the sponsor for the IDE, name the entity or individual who will be the IDE sponsor.**

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent_exoskeleton
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent_exoskeleton_01202022a.pdf(0.17)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent_exoskeleton_large_print
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent_exoskeleton_large_print_version_01202022.pdf(0.05)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent_SO
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Consent_exoskeleton_SO_v1.1.pdf(0.08)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PROC not activated
2. * **Type:**
   Ancillary Committee Approval
3. * **File:**
   PROC neurology not activated.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   VCU Informed Consent Evaluation Tool
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   ICEval.doc(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   MoCA - blind
2. * **Type:**
   Research Measure
3. * **File:**
   MoCA-Test-BLIND - 04-2020.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   NSR Device APDM
2. * **Type:**
   Other
3. * **File:**
   APDM CE 510k exempt.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   APDM User Manual
2. * **Type:**
   Other
3. * **File:**
   APDM MobilityLab_UserGuide.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Keeogo User Manual
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   IFU-006-EN v1.1 Keeogo_ User Manual (USA)_approved.pdf(0.02)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   User Manual
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   IFU-003-EN v1.2_Keeogo_ Clinician Manual_approved.pdf(0.02)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Article for NSR device
2. * **Type:**
   Other
3. * **File:**
   Keeogo in MS open label.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Pre-screen phone script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   prescreen phone script_exoskeleton2.docx(0.02)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent from HM14555
2. * **Type:**
   Other
3. * **File:**
   PMDC registry-May 2019-clean.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Support Group Script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Script for Support Groups 9.16.20.docx(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Demographics exoskeleton
2. * **Type:**
   Research Measure
3. * **File:**
   Demographics exoskeleton.docx(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   References
2. * **Type:**
   Other
3. * **File:**
   References.docx(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PDQ-Carer
2. * **Type:**
   Research Measure
3. * **File:**
   FINAL_PDQ-C_English_UK.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   MoCA
2. * **Type:**
   Research Measure
3. * **File:**
   MoCA.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   UPDRS-Part III
2. * **Type:**
   Research Measure
3. * **File:**
   MDS-UPDRS_Part III.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PDQ-39
2. * **Type:**
   Research Measure
3. * **File:**
   PDQ39.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Berg Balance Scale
2. * **Type:**
   Research Measure
3. * **File:**
   BBS short form.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Hand Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Hand Biosketch.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Baron Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Baron Biosketch.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   IDE Exemption
2. * **Type:**
   FDA Regulatory Document
3. * **File:**
   Keeogo_No IDE Req'd.pdf(0.01)

ID: MS4_HM20020066 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Partial waiver for pre-screens from registry
2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☑	**None of the Above (select waiver below)**

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ Other electronic signature platform

4. If Other is selected, explain:

5. * **Select any waivers that apply to this consent / assent group:**

- [ ] No Waivers Requested
- [x] **Waiver of All Consent or Some Elements in Consent Form**
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [ ] Waiver of All Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
- [ ] Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

- When and where consent will occur
- What will be covered during the consent discussion
- How the consent discussion will occur (e.g. in-person, phone, video conference)
- How you will reconfirm consent on an ongoing basis, if applicable

Registry participants who appear to meet basic inclusion criteria will be contacted and offered participation in this study. Those interested will be scheduled for a study screening visit, at which time they will go through the informed consent process with study staff and will either choose to sign the form or not.

8. Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
- [ ] Removing physical symbols of authority like white coats or police badges
- [x] **Sitting down beside the participant instead of standing over them**
- [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
- [ ] Moving to a more neutral location like a conference room

- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [x] **Other protection(s) not listed here – describe below**
- [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
Participants will be told verbally and in writing on the ICF that participation is voluntary and that they may decline without prejudice to their ongoing care.

10. * **How much time will participants be given to make a decision:**
Indefinite

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS4_HM20020066 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Clinic patients

2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☑	**None of the Above (select waiver below)**

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
- [x] **Not using electronic signature platforms**
- [ ] DocuSign Part 11 (FDA regulated studies)
- [ ] DocuSign (standard platform for non-FDA regulated studies)
- [ ] REDCap e-Consent
- [ ] Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☐	No Waivers Requested
☑	**Waiver of All Consent or Some Elements in Consent Form**
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   If a potential participant is found in the clinic schedule and confirmation of diagnosis is confirmed by reviewing the patient's electronic medical records, the study staff will notify the potential participants provider. The provider will inform the potential participant about the study and provide them with the contact information of the study staff. The potential participant will be able contact the study staff.

8. **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
   - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
   - [ ] Removing physical symbols of authority like white coats or police badges
   - [x] **Sitting down beside the participant instead of standing over them**
   - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - [ ] Moving to a more neutral location like a conference room
   - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
   - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - [x] **Other protection(s) not listed here describe below**
   - [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Participants will be told verbally and in writing on the ICF that participation is voluntary and that they may decline without prejudice to their ongoing care.

10. * **How much time will participants be given to make a decision:**
    They will be allowed to take as much time as needed to read the ICF, ask questions, and make a decision. If they wish to take the informed consent form (ICF) home to think about it, they may do that and return at a later date to enroll in the study.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: MS4_HM20020066 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Caregivers of PD Patient Participants
2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ Other electronic signature platform
4. **If Other is selected, explain:**
5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)
☑	**Research Coordinator**
☐	Research Nurse
☐	Consultant
☐	Research Assistant

- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   Informed consent will be obtained at the start of the visit before any study procedures are done. The consent process will occur in a private exam room.

   After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but before they finish the study, they will be consented again with the most current consent form.

8. **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
   - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
   - [ ] Removing physical symbols of authority like white coats or police badges
   - [x] **Sitting down beside the participant instead of standing over them**
   - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - [ ] Moving to a more neutral location like a conference room
   - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
   - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - [x] **Other protection(s) not listed here describe below**
   - [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   The consent will clearly state that their participation is voluntary, and that they may decline participation without prejudice. As a caregiver, they will also be informed that their participation is not required for the PD patient to take part in the study.

10. * **How much time will participants be given to make a decision:**
    The caregiver will have until the first treatment visit of the PD patient to decide if they want to participate.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
    n/a

ID: MS4_HM20020066 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Assent for Decisionally Impaired Adult

2. * **Select all that apply to this consent / assent group:**

   Name

   - [ ] Signed Consent by Participant

Name
☑ **Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☑ **Signed Assent by Child or Decisionally Impaired Adult**
☐ Verbal Assent by Child or Decisionally Impaired Adult
☐ Short Form Consent (limited applicability)
☐ None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☑ **Not using electronic signature platforms**
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑ **No Waivers Requested**
☐ Waiver of All Consent or Some Elements in Consent Form
☐ Waiver of Parental Permission or Legally Authorized Representative Consent
☐ Waiver of All Assent by Child or Decisionally Impaired Adult
☐ Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐ Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☐ Principal Investigator
☑ **Co/Sub-Investigator**
☐ Medical or Psychological Responsible Investigator
☐ Lead Student/Trainee Investigator (leading their own project)
☑ **Research Coordinator**
☐ Research Nurse
☐ Consultant
☐ Research Assistant
☐ Pharmacist
☐ Statistician
☐ Regulatory Coordinator
☐ Trainee/Student(working on project)
☐ Other
☐ N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

    - When and where consent will occur
    - What will be covered during the consent discussion
    - How the consent discussion will occur (e.g. in-person, phone, video conference)
    - How you will reconfirm consent on an ongoing basis, if applicable

    Consent will be obtained from the Legally Authorized Representative of participants and assent will be obtained by the participant. Information about the study will be provided in oral and written form to the participants, prior to any study activities. Consent conversations will occur in a private room. Visually impaired participants will be given a large print version of the consent.
    After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but before they finish the study, they will be consented again with the most current consent form.

8. **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
    - [x] **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
    - [x] **Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion**
    - [ ] Removing physical symbols of authority like white coats or police badges
    - [x] **Sitting down beside the participant instead of standing over them**
    - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
    - [ ] Moving to a more neutral location like a conference room
    - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
    - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
    - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
    - [x] **Other protection(s) not listed here describe below**
    - [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
    Potential participants will be informed it is their decision to participate and not a requirement to receive clinical care.

10. * **How much time will participants be given to make a decision:**
    Potential participants will be allowed to take as much time as they need to decide. They will be allowed to take the consent form home to review.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
    n/a

ID: MS4_HM20020066 View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
    Potential PD Patient Participants

2. * **Select all that apply to this consent / assent group:**

	Name
[x]	**Signed Consent by Participant**
[ ]	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
[ ]	Signed Assent by Child or Decisionally Impaired Adult
[ ]	Verbal Assent by Child or Decisionally Impaired Adult
[ ]	Short Form Consent (limited applicability)
[ ]	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
    - [x] **Not using electronic signature platforms**
    - [ ] DocuSign Part 11 (FDA regulated studies)
    - [ ] DocuSign (standard platform for non-FDA regulated studies)

- [ ] REDCap e-Consent
- [ ] Other electronic signature platform

4. If Other is selected, explain:

5. * **Select any waivers that apply to this consent / assent group:**

- [x] **No Waivers Requested**
- [ ] Waiver of All Consent or Some Elements in Consent Form
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [ ] Waiver of All Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
- [ ] Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [x] **Medical or Psychological Responsible Investigator**
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

- When and where consent will occur
- What will be covered during the consent discussion
- How the consent discussion will occur (e.g. in-person, phone, video conference)
- How you will reconfirm consent on an ongoing basis, if applicable

Informed consent will be obtained at the start of the visit before any study procedures are done. The consent process will occur in a private exam room. Visually impaired participants will be given a large print version of the consent.

After each study visit, the patient will be asked to continue in the study by confirming their next visit. Participants will be informed of their right to withdraw from the study at any time without prejudice. If a new consent is approved after a participant starts the study but before they finish the study, they will be consented again with the most current consent form.

8. Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion

- [ ] Removing physical symbols of authority like white coats or police badges
- [x] **Sitting down beside the participant instead of standing over them**
- [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
- [ ] Moving to a more neutral location like a conference room
- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [x] **Other protection(s) not listed here – describe below**
- [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
The consent will clearly state that participation is voluntary, and that they may decline participation without prejudice to their ongoing care.

10. * **How much time will participants be given to make a decision:**
They will be allowed to take as much time as needed to read the ICF, ask questions, and make a decision. If they wish to take the informed consent form (ICF) home to think about it, they may do that and return at a later date to enroll in the study.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
n/a

ID: MS4_HM20020066 View: Personnel

Personnel

1. * **Name:**
Mark Baron

2. * **Is this individual a 'COI Investigator'?**

Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

- (●) **Yes**
- ( ) No

3. * **Roles:**

- [x] **Principal Investigator**
- [ ] Co/Sub-Investigator
- [x] **Medical or Psychological Responsible Investigator**
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)

- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [x] **Data Collection - Lab**
- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. Additional or Emergency Phone:

ID: MS4_HM20020066 View: Personnel

Personnel

1. * **Name:**
GinaMari Blackwell

2. * **Is this individual a 'COI Investigator'?**

Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

- ○ Yes
- ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☑ **Other**

4. * **If other role is selected, explain:**
Study Coordinator

5. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**
- ☐ Data Collection - Direct Observation
- ☐ Clinical Services
- ☐ Intervention Services
- ☑ **Data Entry**
- ☑ **Data Coding**
- ☑ **Data Management**

- [ ] Data Analysis
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities
7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

ID: MS4_HM20020066 View: Personnel

Personnel

1. * **Name:**
   Ronald Elswick
2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**
3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator

- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [x] **Other**

4. * **If other role is selected, explain:**
Biostatistician

5. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [ ] Experience - Research

- ☐ Experience - Clinical
- ☐ Experience - Related Skills
- ☐ Trainee
- ☐ Student
- ☐ Other

8. Additional or Emergency Phone: