Human Protocol (Version 1.2)

General Information

*Please enter the full title of your study::		
Mindfulness Based Stress Reduction for Parkinson's Disease: A Longitudinal Study		
***Please enter the Study Number you would like to use to reference the study:**		
MBSR * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.		

Add departments

and Specify Research Location:

Is Primary?	Department Name
◉	**VASDHS** - VASDHS

Assign key study personnel(KSP) access to the study

***Please add a Principal Investigator for the study:**

Schiehser, Dawn M.

3.1 If applicable, please select the Research Staff personnel

A) Additional Investigators

Filoteo, J. Vincent
Co-Investigator
Liu, Lin
Co-Investigator
Wetherell, Julie
Co-Investigator

B) Research Support Staff

Bashor, Kaylee
Research Associate
Bayram, Ece, PhD
Research Associate
Cabrera Tuazon, Angelie
Research Associate
McMann, Tiana

Research Associate
Whiteley, Nicole M.
Study Coordinator

***Please add a Study Contact**

Schiehser, Dawn M.
Whiteley, Nicole M.

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

VASDHS IRB
Human Subjects Protocol
v20190121

Section 1 - Preliminaries

Principal Investigator:

Dawn M. Schiehser

Protocol Title:

Mindfulness Based Stress Reduction for Parkinson's Disease: A Longitudinal Study

IRB Protocol Number:

H190057

Protocol Nickname:

MBSR

Form Template Version:

v20150115

Date Prepared:

08/02/2019

Please be advised that this protocol application form has changed as a result of the 2018 Common Rule. There are new questions and sections, and you may be required to provide additional information to previous sections.

1a) Is this study considered human research?

- (•) Yes
- ( ) No
- ( ) I don't know

1b) Please select:

- (•) This is an application for a NEW human subject research protocol
- ( ) This is a revision of an existing protocol

Section 2 - Research Subjects

2a) What is the total planned number of VA-consented subjects?

Include the total number of subjects who will prospectively agree to participate in the study (e.g., documented consent, oral consent, or other).

88

2b) What is the total number of VA subjects who WILL NOT be consented?

Include the total number of subjects that will be included without consent (e.g., chart review). *Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still should enter the number of charts as your "planned subjects."*

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Section 2.1 Consented Subject Groups

2.1) For each of the subject categories listed below, indicate whether or not these subject groups will participate in the study:

2.1a) Children under the age of 18
Note: If neonates or children will be involved in this study, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

○ Yes ◉ No

2.1b) Pregnant women

○ Yes ◉ No

2.1c) Individuals with cognitive/decisional impairment

○ Yes ◉ No

2.1d) Non-English-speaking individuals

○ Yes ◉ No

2.1e) Prisoners of War (explicitly targeting this group)

○ Yes ◉ No

2.1f) Non-Veterans (Note: Justification for inclusion of non-Veterans will be required)

◉ Yes ○ No

2.1g) Incarcerated individuals (Note: VA CRADO approval will be required)

○ Yes ◉ No

2.1h) VA employees - including VA paid, IPA, or WOC (Note: Union review and authorization may be required)

○ Yes ◉ No

2.1i) Students of the institution (e.g., resident trainees) or of the investigator

○ Yes ◉ No

2.1j) Patients with cancer (or high cancer risk) [explicitly targeting this group]

○ Yes ◉ No

Section 3 - Study Features (these items default to "No" for convenience)

3) This section consists of several Yes/No questions addressing protocol characteristics. Click on *Save and*

Continue.

Section 3.1 Protocol Basics

Select all that apply

3.1a) The research **intends to change** the participant.

(•) Yes ( ) No

3.1b) **Interactions** with living participants to collect data or specimens with no intent to change them.

( ) Yes (•) No

3.1c) This is a study that **never** has any **subject contact and does not collect subject identifiers**

( ) Yes (•) No

3.1d) This is a **chart review** study involving retrospective or prospective medical records.

( ) Yes (•) No

3.1e) This is a **multi-site** study occurring in-part or in-full at other locations.

( ) Yes (•) No

3.1f) There is an **international** component to this research. *International research includes sending or receiving human derived data or specimens (identifiable, limited data set, coded, or deidentified) to or from an international source. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.*

( ) Yes (•) No

3.1g) This study includes **off-station activity** (not including VA-leased space or CBOC clinics) conducted under VASDHS IRB approval. *Note: this does not include research conducted by a collaborator at their home institution under their institutional approval.*

( ) Yes (•) No

3.1h) VA subjects will **participate** in part or in full **at other locations** (not including VA-leased space or clinics) under VASDHS IRB approval. *Note: if this study involves remote participation of subjects, please indicate "no" and describe their remote participation in section 9 of the application. This question is intended to understand whether participants must physically go to a non-VA location to participate in this VA research study.*

( ) Yes (•) No

Section 3.2 Specimen Use and Data Repository

Indicate whether or not each of the following applies to this protocol

3.2a) Involves specimens that are left over from pathological or diagnostic testing (**non-research specimens**)

( ) Yes (•) No

3.2b) Involves **specimens collected for research** purposes **only**

( ) Yes (•) No

3.2c) This study includes **specimen banking** (specimens are retained for use outside of the purposes of this protocol)

( ) Yes (•) No

3.2d) The study involves **DNA** genotyping or other **genetic analysis**

○ Yes ◉ No

3.2e) Biological **specimens/material** will be sent outside of the VA.

○ Yes ◉ No

3.2f) A **data repository** is maintained (data are retained after completion of the protocol for other uses, IMPORTANT: see **?** before checking "yes")

○ Yes ◉ No

3.2g) **Data will be shared outside** of the VA (identifiable, coded, limited data set, or deidentified)

◉ Yes ○ No

Section 3.3 Treatment and Clinical Trials

Indicate whether or not each of the following applies to this protocol

3.3a) Includes a **treatment** component (a research treatment)

◉ Yes ○ No

3.3b) Study is a **clinical trial.** *Note: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.*

◉ Yes ○ No

3.3c) Has a data safety monitoring board (**DSMB)** or data safety monitoring committee.

○ Yes ◉ No

3.3d) Has a **data safety monitoring plan** (but not a DSMB) (this is not the data security plan, it is a safety plan).

○ Yes ◉ No

Section 3.4 Drugs and Devices

Indicate whether or not each of the following applies to this protocol

3.4a) **Drugs** that require **FDA** action such as an Investigational New Drug (IND) approval or exemption or 510 (k) approval.

○ Yes ◉ No

3.4b) Other drugs, supplement, etc. that **do not require FDA** action for inclusion in the study.

○ Yes ◉ No

3.4c) Medical **devices requiring FDA** IDE approval or waiver

○ Yes ◉ No

3.4d) **Other** medical **devices**

○ Yes ◉ No

Section 3.5 Risk and Hazards

Indicate whether or not each of the following applies to this protocol

3.5a) Study places subjects at **greater than minimal risk** (do not include risks that are due to standard care)

○ Yes ◉ No

3.5b) Human subjects are exposed to **radioisotopes** (do not include standard care).

○ Yes ◉ No

3.5c) Subjects have other **radiation exposure** (e.g., x-rays) (do not include standard clinical use).

○ Yes ◉ No

3.5d) Target population has psychiatric diagnosis, behavioral complaint, or chronic pain.

◉ Yes ○ No

Section 3.6 Clinical Facilities and Standard Care

Indicate whether or not each of the following applies to this protocol

3.6a) Study **uses VA clinical services** (e.g., adds required tests run in the VA lab for study purposes; research procedures concurrent with clinical care)

○ Yes ◉ No

3.6b) Includes procedures or drugs that will be considered **part of standard care.**

○ Yes ◉ No

3.6c) Involves **lab tests done for research** purposes.

○ Yes ◉ No

Section 3.7 Subject Expenses and Compensation

Indicate whether or not each of the following applies to this protocol

3.7a) There may be expense or added **costs to the subject** or the subject's insurance.

○ Yes ◉ No

3.7b) This is a **qualifying cancer treatment trial** and subjects may be billed for study drugs or procedures.

○ Yes ◉ No

3.7c) This is a cancer treatment trial but **subjects will not be billed** for study drugs or procedures.

○ Yes ◉ No

3.7d) Subjects will be **compensated** (either in cash or other means such as a gift certificate).

◉ Yes ○ No

Section 3.8 Subject Activities

Indicate whether or not each of the following applies to this protocol

3.8a) Involves **surveys or questionnaires** completed by subjects

◉ Yes ○ No

3.8b) Includes the use of **recruitment materials** such as flyers, advertisements, or letters

◉ Yes ○ No

3.8c) Involves facial **photographs** or audio or video **recordings** of **patients**

(•) Yes ( ) No

Section 3.9 Sponsors and Collaboration

Indicate whether or not each of the following applies to this protocol

3.9a) This research is a funded research project **(commercial (industry) sponsor, NIH, VA, other).**

(•) Yes ( ) No

3.9b) Other **commercial (industry) non-financial support** is provided (e.g., drugs or supplies).

( ) Yes (•) No

3.9d) The protocol has **Department of Defense** involvement (e.g., subjects or funding).

( ) Yes (•) No

3.9c) The PI or other study staff member has a financial interest or other **real or potential conflict** related to this study.

( ) Yes (•) No

3.9e) This study involves **collaborative** research activities (research conducted at other institutions under the authorities or approvals of the other institution/s). *Note: this may include other VA and/or non-VA institutions, but does not include off-site VA research.*

( ) Yes (•) No

Section 4 - Estimated Duration

4) What is the estimated duration of the entire study? (From IRB approval to IRB closure)

5 years

Section 5 - Lay Language Summary

5) Provide a summary or synopsis of the proposed study using non-technical language (not more than 1 paragraph)

The overall aim of this longitudinal RCT is to determine the efficacy of MBSR to improve HRQoL, cognition, and mood, as well as to determine the longevity of the treatment response in individuals with PD. We hypothesize that HRQoL, cognition (particularly executive function), and mood (particularly anxiety) symptoms (will improve in PD participants following eight weeks of MBSR compared to PD participants randomized to an eight-week active Psychoeducational control condition. We further hypothesize that benefits of MBSR treatment will be evident at the 6- and 12-month assessments, such that those completing the MBSR group will demonstrate better HRQoL, cognition, and mood relative to those PD patients who completed the Psychoeducational Supportive Care (PSC) group. Potential mediators/moderators of the treatment response will be examined in exploratory hypotheses. Eighty-eight non-demented individuals with PD will be recruited and enrolled in the proposed study. Over-recruitment by 10% will be instituted to account for subject attrition or unusable data, and to ensure an adequately-powered sample size of 80 (40 per group). Participants will be randomized into either eight weeks of MBSR (n = 44) or eight weeks of PSC (n = 44). All participants will be administered a battery of neuropsychological tests to measure HRQoL, cognition (e.g., executive function, attention, memory), and mood (i.e., anxiety, depression, and apathy), as well as motor symptoms, disease severity, and mindfulness engagement/practice. Tests will be administered at baseline, 8 weeks (post-treatment), and 6- and 12-months (follow-up assessments) by an examiner blinded to group assignment. Data will be primarily analyzed using linear and multivariable random effects modeling. Findings from this study will provide critical information regarding the efficacy of MBSR for HRQoL, cognition, and mood in PD. Furthermore, results will

provide essential data regarding the long-term benefits of MBSR in PD, and elucidate potential mediators/moderators of treatment response.

Section 6 - Specific Aims

6) Provide a statement of specific aims and hypotheses that serve as the basis for this protocol. Emphasize those aspects that justify the use of human subjects.

Aim 1. To investigate the efficacy of MBSR to improve health-related quality of life in PD.
Hypotheses: PD patients who complete MBSR will demonstrate (Primary Hypothesis 1a) greater improvement in HRQoL from baseline to post-treatment compared to PD participants randomized to a duration- and frequency-matched psychoeducational/supportive care control group; and (Hypotheses 1b) better HRQoL at the 6- and 12-month follow-up evaluations.

Aim 2. To examine the efficacy of MBSR to improve cognition in PD.
Hypotheses: PD patients who complete MBSR will demonstrate (Hypothesis 2a) greater improvement in cognition from baseline to post-treatment compared to PD participants randomized to a duration- and frequency-matched psychoeducational/supportive care control group, and (Hypotheses 2b) better cognition at the 6- and 12-month follow-up evaluations.

Aim 3. To determine the efficacy of MBSR in reducing mood symptoms in PD.
Hypotheses: PD patients who complete MBSR will demonstrate (Hypothesis 3a) greater improvement in mood from baseline to post-treatment compared to PD participants randomized to a duration- and frequency-matched psychoeducational/supportive care control group, and (Hypotheses 3b) better mood at the 6- and 12-month follow-up evaluations.

Exploratory Aim: To examine the mediators and moderators of treatment response on HRQoL following MBSR in PD. As cognitive and mood symptoms are associated with poor HRQoL in PD, we hypothesize that HRQoL change will be mediated and/or moderated by changes in cognition and mood from pre- to post-intervention. We will test the possible moderation/mediation effects of non-motor and motor symptoms on HRQoL following MBSR at 8 weeks (post-treatment), and 6- and 12 months.

Section 7 - Background and Significance

7) Provide a succinct discussion of relevant background information to justify performing the proposed study.

Over 80,000 Veterans with Parkinson's disease (PD) currently obtain their medical care within the VA Healthcare System and the number of Veterans with PD is expected to increase in the near future. Health-Related Quality of Life (HRQoL) is severely compromised in those with PD and worsens as the disease progresses. Non-motor symptoms, particularly cognition and mood, which also progressively decline over the course of the disease, contribute to poor and worsening of HRQoL in PD. Interventions that target these symptoms and improve HRQoL are critically needed. Mindfulness-based Stress Reduction (MBSR) is a non-pharmacological intervention that has been shown to improve HRQoL as well as improve mood and attenuate cognitive decline in older adults with and without neurological disorders. Although preliminary evidence supports MBSR as a promising intervention for PD, there has yet to be a comprehensive randomized controlled trial (RCT) of MBSR in this population. Results from our pilot trial (n = 20) demonstrated that PD participants who completed an 8-week MBSR program (n = 8) evidenced an improvement in overall HRQoL (d' = **1.14**), cognition (executive function; d' = **1.6**), and mood (anxiety; d' = **1.1**) compared to PD participants in an active control condition (Psychoeducation/Supportive Care; n = 12); the latter of whom experienced a *worsening* of symptoms. These findings provide convincing preliminary evidence of MBSR efficacy for PD. In the proposed RCT, we will determine the efficacy of MBSR to improve HRQoL, cognition, and mood in a larger PD sample as well as determine the longevity of the treatment response.
Findings from this study will provide critical information about the efficacy of MBSR for HRQoL, cognition, and mood in PD. Furthermore, results will provide essential data regarding the long-term benefits of MBSR for non-motor symptoms in PD and elucidate potential mediators/moderators of the treatment response. Ultimately, this study will test a potential efficacious treatment for PD that could be widely implemented and disseminated throughout the VA Healthcare System and beyond.

Section 9 - Design and Methods

9) Describe the research design and the procedures to be used to accomplish the specific aims of the project. Provide a precise description of the planned data collection (include what systems or databases will be used/accessed to gather data), analysis and interpretation. For chart review studies, include the timeframe of collection. Address sample size, inclusion of women and minorities. Define in clear terms exactly what will be done to the human subjects.

Participants
Eighty eight participants (44 per group) with PD will be primarily recruited from the VA San Diego and secondarily from UCSD (please see recruitment section below for more information regarding recruitment strategy and sites) to ensure a final sample size of 80 (40 per group) after accounting for attrition.

Inclusion criteria:

(1) Clinical diagnosis of Parkinson's disease based on the UK Brain Bank Criteria

(2) >40 years of age

(3) Able to walk or stand without dependence on assistive device

(4) willingness to be audio-taped.

Exclusion criteria:

(1) Secondary causes of Parkinsonism (e.g., corticobasal degeneration, progressive supranuclear palsy, drug-induced parkinsonism)

(2) other neurological conditions (e.g., stroke)

(3) clinical diagnosis of dementia based on any previous neuropsychological testing (pre-screening) or as indicated by neuropsychological testing (consented screening).

(4) psychosis, antipsychotic treatment or treatment for substance abuse (within the past 30 days)

(5) uncorrected vision or hearing to adequately participate in the intervention

(6) Indication of wheel chair bound or bedridden unless aided

(7) prior formal training in MBSR or regular current MBSR practice

(8) active/current participation in a psychological/behavioral treatment, such as Cognitive Behavioral Therapy (CBT)

(9) active/current suicidal ideation as indicated on item #9 of the Beck Depression Inventory (BDI-II; ≥1) and evaluation by a licensed clinician on the protocol.

Procedures:

All participants will be administered an IRB-approved pre-consent telephone screen, which will inquire about the inclusion/exclusion criteria, including PD diagnosis, prior neuropsychological testing, cognitive/dementia diagnosis, and mobility. In the case of an outside referral, a release of information (ROI) may be obtained to confirm the PD diagnosis or other inclusion/exclusion uncertainties. Additionally for outside referrals, we will attempt to minimize patient and provider burden by utilizing existing medical records pertaining to the PD diagnosis (neurological evaluation), with the patient's consent. Individuals who report any previous neuropsychological testing with a subsequent clinical diagnosis of dementia and/or a clinically-obtained MoCA scores below cut off will be excluded. These pre-consent screening questions are implemented to minimize patient burden by limiting the potential for exclusion prior to consent.

The majority of the potential participants who meet the above inclusion criteria (e.g., PD diagnosis, MoCA >20 or clinical diagnosis of dementia, able to walk/stand without dependence on assistive device) will be referred by our Consultant, Dr. Litvan (UCSD), who is a movement disorder specialist and neurologist. All participants will be administered an IRB-approved pre-consent telephone screen, which will inquire about the aforementioned inclusion and exclusion criteria, including PD diagnosis, prior neuropsychological testing, cognitive/dementia diagnosis, and mobility. These pre-consent screening questions are implemented to minimize patient burden by limiting the potential for exclusion prior to consent and testing.

Assessments and Intervention

Upon consent, all potential participants will be administered a health/medical history questionnaire, MoCA, and BDI-II to screen for and confirm inclusion/exclusion criteria. Due to our pre-consent screening procedures, we anticipate that exclusion will be low at this point. However, those who do not meet criteria will be thanked and paid in full for the session. During consenting, the research study personnel will read the informed consent to the participants while they follow along with their own copy. Participants will receive a thorough explanation of the study and study personnel will answer participant questions as they arise. Participants will be administered a decisional capacity assessment to ensure that they understand all parts of the study. If they cannot answer the questions during the assessment the form will be read to them again and the questions will be re-administered. At that point in time, if he/she cannot answer the questions they will be thanked for their time and given referrals as needed. We do not plan on enrolling individuals who are unable to consent (dementia diagnosis is an exclusion) and we will not be requesting any waivers for written informed consent.

Those who meet criteria will be administered the pre-intervention neuropsychological battery within approximately one week prior to beginning the group by an examiner who will be blinded to group assignment. Participants will be group randomized to one of two 8-week conditions (i.e., 6-8 participants assigned in groups via R randomizer to either Mindfulness Based Stress Reduction (MBSR) or Psychoeducational Supportive Care). All activities will be conducted on the VA San Diego campus. MBSR and Psychoeducational Supportive Care groups will each consist of approximately 6-8 individuals with PD and be led by a trained instructor who is not involved in the clinical care or assessment of these participants. Participants will meet in groups for 2.5 hours once per week for eight weeks, with a 2.5 hour session ("retreat") between weeks 6 and 7. Each week and at the start of group, all participants will complete a brief form regarding changes in mood and medications. Any changes in mood will be addressed by clinicians on the protocol to assess for SI (please see MCM 11-24 Suicidality attached to protocol). We will offer assistance during each session to escort those who are at risk for falling (i.e., UPDRS fall item #13 > 0) to the bathroom and to and from their vehicle as appropriate.

All participants will be administered a battery of neuropsychological tests to measure HRQoL, cognition (e.g., executive function, attention, memory), and mood (i.e., anxiety, depression, and apathy), as well as motor symptoms, disease severity, and mindfulness engagement/practice. The UPDRS Part-III/Hoehn and Yahr Score (HYRS), which assess level of motor function and characterizes disease severity, will also be administered by study staff, certified in UPDRS administration, at their baseline assessment. If we are unable to obtain this score, we will obtain a ROI to access their UPDRS exam score(s) and HYRS. Tests will be administered at baseline, 8 weeks (post-treatment), and 6- and 12-months (follow-up assessments). Breaks will be offered and given during the assessment as needed. Study questionnaires are attached to the protocol submission.

Following the intervention and 6- and 12-months post-intervention, PD participants will be re-tested by a group-blinded research assistant. The UPDRS Part-III/HYRS will also be administered by study staff, certified in UPDRS administration, at the 12-month follow up appointment as well. Total participation time is 2-3 hours per session x 4 total sessions (-pre, -post, -6, and -12 month follow up). To better retain participants throughout the 12-month trial period, we will implement friendly reminder calls at 2-months and 1-month prior to each testing session as well as send a reminder letter with pertinent information (e.g., directions) 2-3 weeks prior to their appointment. In addition, MBSR will be offered to the Psycheducational Supportive group participants upon study completion.

Database

We will be using HIPAA compliant VA system REDCap. Security features include that the website is accessible only on a VA computer, through the VA network and requires VA Network ID. Data is backed-up nightly and every six hours. Once verified and approved through the VA, staff will access the REDCap database through the aforementioned security features. Research staff listed in the protocol will have access in Redcap.

Data Analysis

Data will be primiarily anaylzed using linear and multivariable random effects modeling.

Section 9.8 Questionnaires & Surveys

9.8) Provide the name and a reference for questionnaires/surveys that are standard or identify them here and attach a copy of the questionnaire/survey. ***Questionnaires or surveys that are not clinical standard references must be uploaded. Reference the help link for additional information related to surveys administered to VA personnel and approved platforms for web-based surveys.***

Beck Depression Inventory (BDI-II)

The Parkinson's disease Questionnaire-39 (PDQ-39)

Spielberger State-Trait Anxiety Inventory (STAI/TRAIT)

Geriatric Depression Scale (GDS)

Starkstein Apathy Scale (AS)

Five Facet Mindfulness Questionnaire (FFMQ-15)

Credibility and Expectancy Questionnaire (CEQ)

Client Satisfaction Questionnaire (CSQ-8)

Mindfulness Based Stress Reduction Practice Log

Section 9.11 Pictures and Audio/Video Recordings of Patients

9.11) Describe the purpose of photographs (facial), or audio, or video recordings of patients. Describe whether the recordings will contain, or potentially contain, identifiers. ***Note: use of photographs or recordings must be covered in the informed consent process and documented consent documents (e.g., consent form, information sheets, telephone screen scripts).***

All sessions of MBSR and Psychoeducation/ Supportive Care will be audiotaped and available for rating in order to ensure fidelity and integrity of the protocol administration. All first sessions and a random sample of 10% of the audiotapes for the MBSR intervention will be reviewed by supervisors. Dr. Filoteo will also aid in the fidelity checks for the Psychoeducation intervention. Group facilitators will be provided corrective feedback, if needed. The facilitator will monitor attendance and note individual level of participation. Audio recordings will be destroyed at the end of the study. Audio recordings transferred into a computer system will be assigned group numbers and will not be individually identifiable. The key that relates the group numbers to the individuals will be stored separately, protected by strong passwords, and accessible only by approved study personnel. Recording members refer to each other by first name only, to ensure that they remain unidentifiable. Credibility, expectancy, engagement, practice, and facilitator competency will be examined in analyses.

We will also be video recording some of the group sessions. If 100% of group members agree to be recorded, we may video-record their group. If some of the subjects decline to be videotaped then we will not proceed with recording their session. Study participants may agree to such voluntary recording, or not, without any effect on the rest of their participation in the study.

Section 10 - Human Subjects

10) Describe the characteristics of the proposed subject population. Include age, gender, ethnicity, and health status as appropriate. ***Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still describe the characteristics related to the subjects whose charts you will review.***

- **Provide inclusion and exclusion criteria as appropriate. Provide a statement how non pregnancy is confirmed if pregnancy is an exclusion criteria.**

- **For multisite studies, provide the total number of subjects from all sites and include description of the local site's role as a coordinating center if applicable.**
- **Indicate the number of VA participants to be studied.**
- **Indicate the estimated number of consented subjects that will fail the screening process, if any.**

Eighty-eight non-demented individuals with PD will be recruited and enrolled in the proposed study. Over-recruitment by 10% will be instituted to account for subject attrition or unusable data, and to ensure an adequately-powered sample size of 80 (40 per group).

Inclusion criteria includes:
(1) Clinical diagnosis of PD based on the UK Brain Bank Criteria
(2) >40 years of age
(3) Able to walk or stand without dependence on assistive device
(4) willingness to be audio-taped.

Exclusion criteria includes:
(1) Secondary causes of Parkinsonism (e.g., corticobasal degeneration, progressive supranuclear palsy, drug-induced parkinsonism)
(2) other neurological conditions (e.g., stroke)
(3) clinical diagnosis of dementia based on any previous neuropsychological testing (pre-screening) or as indicated by neuropsychological testing (consented screening).
(4) psychosis, antipsychotic treatment or treatment for substance abuse (within the past 30 days)
(5) uncorrected vision or hearing to adequately participate in the intervention
(6) Indication of wheel chair bound or bedridden unless aided
(7) prior formal training in MBSR or regular current MBSR practice
(8) active/current participation in a psychological/behavioral treatment, such as Cognitive Behavioral Therapy (CBT)
(9) active/current suicidal ideation as indicated on item #9 of the Beck Depression Inventory (BDI-II; ≥1) and evaluation by a licensed clinician on the protocol.

For all participants in this study, no exclusions will be made based on gender, race or ethnic background. Demographics will be analyzed for each group; should differences be apparent, these variables will be used as covariates in the analyses. As Veterans are mostly male and non-Hispanic white, non-Veterans recruited in order to increase our enrollment of females and ethnic minorities. This is necessary to closely match the prevalence of females (39%) and ethnic minorities (29% Hispanic; 21% Asian, and 19% Black) within PD. We attempt to recruit as many veterans as possible.

Section 10.1 Non-Veteran Subjects

10.1a) Recruitment of non-Veterans cannot be for the sake of convenience for this study. Provide the objective and justification for the inclusion of non-Veteran subjects. Identify how the research results will be generalizable to the Veteran population. ***NEW: ORD now requires completion of a Request to Enroll Non-Veterans form (available in the help section of OnRAMP) for any VA studies requesting to enroll non-Veterans. This form will be reviewed by the local RDC before the application may be considered by the IRB. Complete the form and upload with this submission.***

As Veterans are mostly male and non-Hispanic white, non-Veterans recruited in order to increase our enrollment of females and ethnic minorities. This is necessary to closely match the prevalence of females (39%) and ethnic minorities (29% Hispanic; 21% Asian, and 19% Black) within PD.

10.1b) Non-Veterans must be given a copy of the VA Notice of Privacy Practices (NOPP) and sign the acknowledgement form when their health information is used/collected for research purposes. In addition, the Privacy Officer must be notified of the non-Veteran enrollment and be provided with a copy of the signed NOPP, when applicable. If CPRS notes are entered, and the acknowledgement must also be scanned into CPRS. ***The NOPP, Acknowledgement form, and instructions to provide the completed form to the PO are available under the ? at the top right corner of this page.***

◉ Agree ○ Disagree

Section 11 - Recruitment

11) Describe, step-by-step, the plans for recruitment of subjects (or selection of subjects as in record review). This description must include how, when, and where potential subjects are approached as well as procedures for identifying potential participants (through medical records, physician referral, third-party sources, etc.). Include how selection is equitable. Indicate if vulnerability to coercion may be present and if so plans to ensure voluntary participation.

Recruitment will take place mainly at the VA San Diego. To increase the number of women and minorities, recruitment will also occur at associated clinics, UCSD, and community resources such as PD support groups, other San Diego area hospitals, private clinics, and the community. Recruitment methods include obtaining referrals through VA San Diego's Neurology and Neuropsychology Clinics, posting flyers and electronic media advertisements, participating in PD-related events, and utilizing active support groups and medical professional contacts. In the case of an outside referral, a release of information (ROI) will be obtained to confirm the PD diagnosis.

Participants will be primarily recruited from the VA San Diego Healthcare System (VASDHS). Co-Investigator Dr. Filoteo is a supervisor within the VA San Diego Neuropsychology Assessment Unit, which routinely evaluates PD patients. Dr. Filoteo will refer patients from this clinic as well as from his research lab and UCSD clinics. To increase the number of women and minorities, we will also recruit through additional sites, including UCSD and community resources such as PD support groups, other San Diego area hospitals, private clinics, and the community. Dr. Litvan (Consultant) is the Director of the Movement Disorder Clinic Center of Excellence at UCSD; she will provide additional referrals as needed. Additionally, recruitment may also take place at outside clinics and hospitals (i.e. Scripps and Sharp Healthcare Systems) and various community centers.

Potential subjects may also be recruited by a search of ICD codes for Parkinson's disease in CPRS. Any patients not previously referred to our study from VASDHS clinics aforementioned, who may be eligible for the study, will be notified via the uploaded Recruitment Letter that a research assistant on this protocol will be contacting them approximately 2 weeks from the day the letter is sent. A research assistant will then call the patient to explain the study and gauge interest in participating. If the patient indicates that they are not interested, the research assistant will thank them for their time and will not contact them again regarding the study. Similarly, potential subjects may be recruited from co-investigators' research studies previously completed (e.g., Dr. Filoteo or Dr. Schiehser's research studies). If a research participant who is potentially eligible for our study indicated in the previously completed research study that they would like to be contacted for future research opportunities, he or she will be informed of our research opportunities via phone call by a research assistant. If the patient indicates that they are not interested, the research assistant will thank them for their time and will not contact them again regarding the study. If the subject continues to show interest in participating, he or she will be informed that they will be asked a series of screening questions to determine their potential eligibility for our study (see attached Phone Screen document).

All potential participants will call or meet with a member of the research team who will explain the study's purpose and answer any questions. If the individual expresses interest in the study, they will be administered an IRB-approved pre-consent telephone screen, which will inquire about the inclusion/exclusion criteria, including PD diagnosis, prior neuropsychological testing, cognitive/dementia diagnosis, and mobility to determine eligibility.

Section 11.1 Recruitment Materials

11.1) Identify all recruitment materials (flyers, advertisements, letters, etc.) that will be used; include the web address for any web-based advertisements. The text of all communications with prospective participants must be reviewed and approved by the IRB before it can be used. You will be reminded to attach copies of recruitment materials to the initial submission packet. ***Note: Posting of flyers with pull tabs is not permitted within VASDHS (including the VMRF building). However, you may request to advertise on the e-boards (located at the elevators and throughout the facility) or on the VASDHS Research Opportunities web-page.***

Recruitment will take place mainly at the VA San Diego. Recruitment will also occur at associated clinics, UCSD, and within the San Diego community. Recruitment methods include:

1. Obtaining referrals through VA San Diego's Neurology and Neuropsychology Clinics
2. Handing out brochures
3. Posting electronic media advertisements
4. Participating in PD-related events, utilizing active support group, and medical professional contacts.
5. Attending various Parkinson's disease community events (i.e. Parkinson's disease walk, exercise classes, support groups)
6. Advertising via VASDHS Hospital TV monitors calling for potential research participants (please see attached VA monitor slide).
7. Advertise our study on appropriate online websites, such as the Michael J Fox Trial Finder (foxtrialfinder.michaeljfox.org). The same wording as the handouts will be used for these announcements.

Patients will also be recruited from other studies completed if they had indicated they would like to be contacted for future research opportunities.

Section 12 - Informed Consent

12) Indicate whether or not each category of consent is involved in this study:

12a) Will the study team obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without (or prior to) obtaining informed consent of the prospective subject or the prospective subject's LAR?

(•) Yes ( ) No

Check one or both of the below boxes if they apply to this study:

Information will be obtained through oral or written communication with the prospective subject or the subject's Legally Authorized Representative (LAR) and this is not a FDA regulated study.

(•) Yes ( ) No

Identifiable information or biospecimens will be obtained by accessing records or stored identifiable biospecimens and this is not an FDA regulated study.

( ) Yes (•) No

If either or both of the above boxes is checked "yes", an informed consent waiver does not have to be requested for this activity if the protocol is initially approved after 01/01/2019 or if it has been converted to the 2018 Common Rule requirements. However, a request for a HIPAA waiver will still need to be requested and informed consent obtained for any research interventions after eligibility is established. Otherwise, waivers of consent and authorization must be requested for this activity. Waivers of consent and authorization are required for screening purposes for FDA regulated research.

12b) **Signed** informed consent

(•) Yes ( ) No

12c) Waiver of documented consent (e.g., **oral** consent) for all or part of the study.

( ) Yes (•) No

12d) Request for a **waiver** of consent for all or some study activities.

( ) Yes (•) No

12e) Alteration of **other required elements** of consent.

( ) Yes (•) No

12f) **Child** assent to participate (Director approval will be required)

( ) Yes (•) No

12g) Will any language **other than English** be used by those obtaining consent and understood by the prospective participant or the legally authorized representative?

○ Yes ◉ No

12h) **Decisional Capacity Assessment** to determine if participants have the capacity to consent for themselves.

◉ Yes ○ No

12i) **Surrogate** consent (legally authorized representative)

○ Yes ◉ No

Section 12.1 Informed Consent Process

12.1a) Will consent be obtained before any study procedures are performed (including screening procedures except screening procedures with Consent and/or HIPAA waiver when required)?

◉ Yes ○ No

12.1b) Will the information being communicated to the participant or legally authorized representative during the consent process include exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or release or appear to release the Researcher, Sponsor, the VA or its agents from liability for negligence.

○ Yes ◉ No

12.1c) A master list of all VA subjects consented (written or not) under this protocol will be maintained.

◉ Agree ○ Disagree

12.1d) Identify the circumstances under which consent will be obtained including where the process will take place; any waiting period between describing the research and obtaining consent including sufficient time for the prospective participant to consider participation, and any steps taken to minimize the possibility of coercion or undue influence.

Informed consent will be obtained at the time of initial visit and the baseline (pre-intervention) evaluation will be conducted.

All potential participants will call or meet with a member of the research team who will explain the study's purpose and answer any questions. If the individual expresses interest in the study, they will be pre-screened to determine eligibility (e.g., PD diagnosis, history of dementia, mobility). If pre-screening eligibility is adequate for inclusion, they will be consented and the baseline (pre-intervention) evaluation will be conducted.

During consenting, the research study personnel will read the informed consent to the participants while they follow along with their own copy. Participants will receive a thorough explanation of the nature of the intervention, how participants will be randomly assigned to one of the intervention groups, their study involvement duration, compensation for their participation, possible risks and benefits, and potential alternative treatments. Study personnel will answer participant questions as they arise. Additionally, participants will be administered a decisional capacity assessment to ensure that they understand all parts of the study. If they cannot answer the questions during the assessment the form will be read to them again and the questions will be re-administered. At that point in time, if he/she cannot answer the questions they will be thanked for their time and given referrals as needed. We do not plan on enrolling individuals who are unable to consent (dementia diagnosis is an exclusion) and we will not be requesting any waivers for written informed consent.

Section 12.6 Decisional Capacity Assessment

12.6a) Describe the method(s) for determination of decisional capacity: (see ? for guidance) ***Please note that documentation of the assessement is required.***

Participants will be administered a decisional capacity assessment to ensure that they understand all parts of the study. If they cannot answer the questions during the assessment the form will be read to them again and the questions will be re-administered. At that point in time, if he/she cannot answer the questions they will be thanked for their time and given referrals as needed. We do not plan on enrolling individuals who are unable to consent (dementia diagnosis is an exclusion) and we will not be requesting any waivers for written informed consent.

12.6b) If subjects with limited decisional capacity will be enrolled, describe methods for obtaining subject assent or why they are not indicated:

Subjects with limited decisional capacity will not be enrolled in the study.

12.6c) If subjects with limited decisional capacity will be enrolled, describe procedures for respecting subject dissent and any additional safeguards or why these features are not needed:

n/a

12.6d) If subjects with limited decisional capacity will be enrolled, describe the risk and, if greater than minimal, the relation to potential benefits:

n/a

12.6e) If subjects with limited decisional capacity will be enrolled, describe the justification for the inclusion of any incompetent persons or persons with impaired decision-making capacity:

n/a

Section 12.9 HIPAA Authorization

For each category below, indicate whether or not this study involves the indicated process:

12.9a) **Signed** HIPAA Authorization. ***New Template is available in the ? Help section***

(•) Yes ( ) No

12.9b) HIPAA waiver to cover the entire study

( ) Yes (•) No

12.9c) HIPAA waiver for recruitment, screening, and/or for a portion of the study.

(•) Yes ( ) No

12.9d) HIPAA Authorization or waiver is **not required** for some or all of the study subjects (e.g. no health data).

( ) Yes (•) No

Section 12.10 HIPAA Waivers and Alterations

12.10a) Describe the purpose/nature of the HIPAA waiver or alteration and list specifically, what identifiers and health information are being requested under the waiver/alteration and identify whether the waiver is for access, use, and/or collection of this information.

1) The waiver will be used to conduct a brief phone screen on potential patients referred to the

study from outside the VASDHS as referenced in section 9. The phone screen will be used to determine eligibility for the study so that potential participants do not waste time and unnecessary hardship traveling to the VASDHS. The study could not be practically conducted without the waiver and without access to and use of PHI.

The subjects will be screened via phone call to determine eligibility to participate. Contact information will also be collected to provide potential participants information on the study and follow-up with eligibility. The data that will be collected under the waiver will include:
-Name
-Mailing address
-Phone number(s)
-Veteran status
-Neurological diagnosis
-Age
-Gender

Immediate inclusion/exclusion questions include:

1. Do you have a history of a stroke?
2. Have you ever been diagnosed with any neurological condition (other than PD)?
3. Has your PD diagnosis been confirmed by a neurologist?
4. Do you have a history of Post Traumatic Stress Disorder (PTSD)?
5. Do you have any psychiatric or mental health diagnosis?
6. Any history of alcohol or substance abuse?
6a. Do you currently use alcohol? Amount/frequency?
6b. Current substance use? Amount/frequency?
6c. Last time you consumed/used?
7. Do you have a history of memory problems or have you been diagnosed with dementia?
8. Have you ever had neuropsychological testing done before?
9. Any major changes in medications within the last month (or anticipated within the next month)?
10. Have you ever had surgical treatment for Parkinson's disease (i.e. DBS surgery)?
11. Do you have any vision, hearing or movement problems that could interfere with taking tests, reading, or interacting in a group setting?
12. Have you ever acquired a major head injury?
13. Are you able to walk unassisted or do you use an assistive device (i.e. cane, walking stick, wheelchair)?
14. Are you trained or currently participating in any Mindfulness Based Stress Reduction practice?
15. Are you currently undergoing any psychological/behavioral interventions or therapies (i.e. Cognitive Behavioral Therapy)?
16. Do you have a history of a brain tumor?
17. Do you have a history of epilepsy or seizures?

2) The waiver will also be used to recruit potential study participants through the Neuropsychology, Neurology, and other relevant clinics at VASDHS. Patients who may be interested will be asked to sign a Research Candidate Form while at clinic, and a research assistant will contact them if they indicate on the form that they agree to be contacted. Additionally, the provider may inform the research team of a potential study participant. At that point, a research assistant will either go speak to the patient in person about the study if the patient expresses interest in meeting with study staff, or will send the patient a letter (uploaded in protocol documents) stating that we will be calling them about a research opportunity.

2b) The Research Candidate form asks for the patient's name, provider name, appointment day /time, and telephone number (if they indicate they would like to be contacted). Calling the subject will require patient's name and telephone number to later be contacted.

3) The waiver will also be used to reach potential study participants through CPRS (using the ICD codes for Parkinson's disease). For any patients who may be eligible, who were not previously referred to the research team by the clinician and did not sign a Research Candidate Form, will be sent a letter informing the patient that we will be calling them about a research opportunity. Sending a letter will require patient's name, mailing address, and telephone number to be contacted in the future.
3b) Recruiting by ICD code search requires knowing the patient's medical diagnoses (of Parkinson's disease). Sending the letter and making a follow-up phone call will require the patient's name, mailing address, and telephone number.

4) Finally, the waiver will also be used to reach potential study participants through previously completed research studies, if they had agreed to be contacted for future research opportunities. Any patients who may be eligible will be called to inform them of our new research opportunities.

This will require the patient's name, mailing address, and telephone number to be contacted in the future.

12.10b) The proposed access, use, and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.

(•) Agree ( ) Disagree

12.10c) The plan to protect the identifiers from improper use and disclosure is adequate.

(•) Agree ( ) Disagree

Describe the plan

Participant identity will be coded immediately upon entry into the study, and neither the participants' names nor any identifying information will be present in the data set. Study records entered into a computer system will be assigned code numbers and will not be individually identifiable. The computerized system where data will be stored will not leave the protected VA environment unless the data storage components are removed or destroyed. Data collected in other areas (testing rooms) will stored in a locked cabinet that is maintained in a locked office (room 332 VMRF or room 306B VMRF) within the VA. Computer data will be protected by strong passwords and accessible only by study personnel. Data will be regularly backed up and the back up stored in a separate locked area controlled by the investigator (room 332 VMRF or room 306B VMRF).

The key that relates the code numbers to the individuals will be will be stored in a stand-alone (non-networked) computer system that is maintained in a locked office within the PI's lab space in Building #13 of the VA San Diego, protected by strong passwords, and accessible only by approved study personnel. This system will not leave the protected VA environment unless the data storage components are removed or destroyed. Hardcopy SI will also be stored for backup purposes in the PI's laboratory within Building #13 of the VA San Diego, in a locked cabinet. Code-numbered data will be stored in a separate filing cabinet under lock and key in Building #13. All SI related to this study will be destroyed in accordance with RCS-10 and under the direction of the VA Records Control Manager.

In the event of a real or suspected breach of security, the VA Police, the VA Information Security Officer, and the VA Privacy Officer will be notified.

12.10d) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

(•) Agree ( ) Disagree

12.10d2) Describe the plan:

SI, such as subject's medical diagnosis, will be used for the purpose of enrollment and subject's personal information, such as age, gender, and education, will be used to characterize the subject pool utilized in this study. Addresses and telephone numbers will also be collected as a means to contact the subjects for follow-up when indicated. All data used in this study will be de-identified and linked to SI by a subject number. Hard copy SI will also be stored for backup purposes in the PI's lab, within Building #13

Data will be destroyed according to RCS-10 under Records Control Manager guidance.

12.10e) By signing this protocol for submission, the PI is providing written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. 38 U.S.C. 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), by signing this protocol for submission the PI is providing written assurance that the purpose of the data is to conduct scientific research and that no personnel involved may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. (Ref: 38 U.S.C. 7332(b)(2)(B))

◉ Agree ○ Disagree

12.10f) The research could not practicably be conducted without the waiver or alteration.

◉ Agree ○ Disagree

12.10f2) Describe how the waiver/alteration enables the research to be conducted

Without the phone screen for contact information and brief exclusionary criteria there would be no feasible way for us to send participants directions and appointment confirmation. There would also be potential for many participants to travel to VASDHS to participate in the study, sign a consent form only to find out they are ineligible for the study and be excused. This would waste the time of the participant as well the VASDHS.
The ability to contact VA patients directly will allow us to recruit more veterans to be enrolled in the study. Additionally, the ability to access medical diagnoses consistent with study inclusion criteria will reduce burden on potential study participants as we will not have to schedule additional appointments or testing to verify diagnoses of these patients. This will also reduce burden on clinicians who may not have time to recruit patients during busy clinic duties and will expand access to these services for Veterans who may not have any upcoming clinic visits in the near future.

12.10g) The research could not practicably be conducted without access to and use of the PHI.

◉ Agree ○ Disagree

12.10g2) Describe why it would be impracticable to conduct this research without the PHI described 12.10a. (v3 /8/18)

1) The data collected by the waiver/alteration (phone screen) is necessary to determine study eligibility.

2) The research candidate form allows research assistants on this protocol to call the patient and recruit them for the study, if interested and eligible. This form provides the means to contact the patient.
2b) The patient's name and contact information will be required for calling patients who were not presented the opportunity to sign the form (this includes subjects previously enrolled in other studies). The patient's phone number will be required to contact the patient.

3) Accessing medical diagnoses in CPRS allows the research team to focus recruiting attention on those who are likely eligible (i.e., a veteran with Parkinson's disease). Additionally, having access to this information reduces participant burden; Veterans will not be scheduled for multiple testing sessions (through research and clinical services) and we will not have to schedule additional appointments or additional testing to verify diagnoses, as they are already listed on file. Furthermore, this will allow us to expand recruitment to Veterans who may not otherwise be reached within targeted clinics at VASDHS

Section 13 - Alternatives to Participation

13) Describe the alternatives to participation in this research study (see ? for guidance)

The alternative to participating is to not participate.

Section 14 - Potential Risks

14) Describe any potential or known risks or discomforts and assess their likelihood and seriousness (see ? for guidance)

This study does not present any major or serious risks beyond those commonly associated with standard behavioral interventions and neuropsychological testing. The neuropsychological tests and motor examinations are typically used in the clinical management of PD patients. Though the risks are relatively minimal, all participants will be informed of the possibility of experiencing potential risks during the informed consent process.

Risks involved with neuropsychological testing and the interventions (MBSR and Psychoeducation/ Supportive Care) are minimal; however, there is the potential that participants may become fatigued, nervous, bored and/or frustrated during the neuropsychological testing (i. e., cognitive assessment and self-report questionnaires) sessions and/or interventions (MBSR or Psychoeducation/Supportive Care). There is also a possible risk that the interventions may cause an increase in negative emotions due to becoming more aware of certain aspects of their disease or lives. There is no requirement to share personal or mental health information but there may be a risk of loss of confidentiality due to the interventions happening in a group setting. Additionally, individuals may also experience emotional discomfort while answering self-report /emotion/mood questionnaires.

Given the age and medical condition (i.e., Parkinson's disease) of the participants, it is possible that individuals may experience medical or psychological changes unrelated to the study that would necessitate early termination of the study.

Section 15 - Risk Management

15) Describe the procedures for protecting against or minimizing any potential risks/discomforts, and the adequacy of resources for conducting the study and resources participants may need as a consequence of the research. When applicable, include detail of the following safety measures: (a) The type of safety information to be collected, including AEs; (b) Frequency of safety data collection; (c) Frequency or periodicity of review of cumulative safety data; (d) Statistical tests for analyzing the safety data to determine if harm is occurring; and (e) Conditions that trigger an immediate suspension of the research. See ? for further requirements.

This study does not present any major or serious risks beyond those commonly associated with standard behavioral interventions and neuropsychological testing. The neuropsychological tests are typically used in the clinical management of PD patients. Though the risks are relatively minimal, all participants will be informed of the possibility of experiencing potential risks during the informed consent process.

To ensure the safety and comfort of all subjects, rest breaks are offered during the neuropsychological evaluations and the intervention groups. Participants will also be free to ask for additional rest breaks or other accommodations to increase tolerability of testing and participation. Participants will be permitted to discontinue the testing or intervention at any time for any reason as stipulated in the Human Subjects IRB consent form. All group participants, however, will be strictly instructed on the need for confidentiality related to group membership and group proceedings.

Given the age and medical condition (i.e., Parkinson's disease) of the participants, it is possible that individuals may experience medical or psychological changes unrelated to the study that would necessitate early termination of the study. If the individual situation warrants, participants may be able to rejoin a later group. Because both interventions (Psychoeducation/Supportive Care and MBSR) are not group therapy, there is no requirement that individuals will share personal and/or mental-health information. However, should any information be conveyed that causes study staff to be concerned about that participant's psychological well-being, appropriate referrals to the VA Geropsychiatry Clinic may be provided to veterans, or other appropriate community resources for veterans and non-veterans will be provided.

Due to the fall risk associated with individuals with PD, we will use the baseline MDS-UPDRS falling item (#13) in which a history of falls is categorized on a Likert scale from 0 (none) to 4 (falls >once per day). A history of falls as assessed by the MDS-UPDRS appears to be one of the best predictive methods of subsequent falls at this time. Those individuals who endorse a history of falling or score >0 on the MDS-UPDRS falling item, will be closely monitored. Should an individual who is at risk for falling be identified, we will offer assistance during each class to escort the individual to and from the intervention room, from their vehicle, as well as to and from the bathroom, if needed. As standard in MBSR, all participants will be encouraged to work within their own personal limits and preferences. Alternatives to the standard exercises will be offered. These alternatives include sitting in a chair in lieu of floor exercises; lying down for standing exercises; omitting certain (e.g., walking) meditations; and/or visualizing the movements in lieu of acting them out. These options are standard in MBSR and have also been implemented in other trials of MBSR for PD.

Suicidal ideation (SI) will be assessed by Beck Depression Inventory (BDI-II) item #9 at each assessment (i.e., pre-, post-, 6- and 12-months). Should an individual indicate ≥ 1 on the BDI-II item 9, the tester will immediately notify a licensed clinician on the protocol. The clinician will

conduct a thorough clinical evaluation of SI to determine appropriateness to continue in the study and provide any necessary referrals. In addition, each week during the intervention, the participants will complete a brief form which will contain two questions regarding changes in mood and medications. Should a participant indicate mood changes, mood and SI will be evaluated by a licensed clinician to determine appropriateness to continue in the study.

Data Security
A tertiary risk might include unintentional disclosure of confidential test information, but confidentiality will be strictly maintained in data storage, manipulation, and presentation.

This study will collect PHI (i.e., data, in any format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration or destruction) from all participating subjects. PHI used in this study will include individually identifiable medical and health data and personal information, such as age, educational level, gender and ethnicity. Subjects' medical diagnoses will be used for the purpose of enrollment and personal information, such as age, gender, and education, will be used to characterize the subject pool utilized in this study. Addresses and telephone numbers will also be collected as a means to contact the subjects for follow-up when indicated. Participant identity will be coded immediately upon entry into the study, and neither the participants' names nor any identifying information will be present in the data set. The computerized system where data will be stored will not leave the protected VA environment unless the data storage components are removed or destroyed. Data collected in other areas (testing rooms) will be brought to the lab and locked away each night. Only approved study personnel will have access to this information.

Presentation of the results will involve group data and the subjects' identity will not be disclosed. In the event of a real or suspected breach of security, the VA Police, Information Security Officer, and the Privacy Officer will be notified. Overall, the proposed study poses no significant increase in risk than what would normally be present in proper clinical management of and frequently prescribed psychological treatment and medical procedures (e.g., UPDRS motor exam) for PD patients.

Adverse Events (AE) and Serious Adverse Events (SAE), as defined below, will be monitored throughout the study duration.
An Adverse Event (AE) is any untoward physical or psychological occurrence in a human subject participating in research. A related AE, death, or problem is an AE, death, or problem that may reasonably be regarded as caused by, or probably caused by, the research.

A Serious Adverse Event (SAE) is an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome.

SAEs are not anticipated as the interventions and tests that will be used are often prescribed in the standard clinical management of patients (i.e., neuropsychological testing, behavioral interventions). Potential AEs include the (1) need to break confidentiality, (2) loss of data for any reason, and (3) inadvertent harm caused by participation in the study. Suicidality in PD patients is typically a rare occurrence, however, patient suicidality will be assessed and monitored throughout the duration of the study. If the need to break confidentiality arises or data is lost the participant and VA IRB will be notified immediately.

AEs and SAEs will be documented and reported to VA IRB, and clinically managed as appropriate, including participant hospitalization if necessary. For each event that occurs, we will create a report that includes the date of the occurrence, description of the event, how it was reported and to whom, as well as any other pertinent information (i.e. medical related information of the incident).

Section 17 - Potential Benefits

17) Discuss benefits that may be gained by the subject as well as potential benefits to society in general (see ? for guidance)

While there is always the potential that participants will not receive any direct benefit from participating in this study, there is also the probable likelihood, based on our preliminary data and previously published research, that participants will experience improvements in quality of life and/or non-motor symptoms, such as cognition and mood. Even if participation in this study does not provide any direct benefits to the participants, their participation will help advance our knowledge regarding the effects of MBSR in PD.

Section 18 - Risk/Benefit Analysis

18) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

The primary risks of participating in this study are fatigue, test anxiety, and emotional discomfort. As noted above, there are specific plans in place to lessen the likelihood of any of these potential risks.

To the best of our knowledge, the risk/benefit ratio appears to be reasonable in relation to the anticipated benefits to be gained by the participants and others. The study involves minimal risk and most participants are eager to contribute to furthering Parkinson's disease research.

Section 20 - Compensation for Participation

20) Provide all details and justifications of the compensation plan. See ? for detailed requirements.

Participants will receive a payment of $75 for each of the four neuropsychological testing sessions they complete (pre- and post-intervention/support and 6- and 12-month follow-ups).

Section 21 - Responsibilities and Qualifications

Here are the identified study staff members

Dawn M. Schiehser

J. Vincent Filoteo, Julie Wetherell, Lin Liu, Nicole M. Whiteley, Angelie Cabrera Tuazon, Ece Bayram, PhD, Kaylee Bashor, Tiana McMann

21) For each staff member listed above, describe their role and qualifications. Also indicate which of the study staff are authorized to obtain consent, when applicable to the study.

The Mindfulness Based Stress Reduction (MSBR) groups will be held at the VASDHS. All staff will be trained and closely supervised by Dawn Schiehser, Ph.D., research health scientist at the VASDHS and a licensed psychologist in the state of California.

Dr. Dawn Schiehser, PhD, Project Director/Principal Investigator. Dr. Schiehser is Research Health Scientist at the VASDHS, an Associate Professor in the Department of Psychiatry at the University of California San Diego (UCSD). She has expertise in the neuropsychology, neurocognitive impairment, rehabilitation, and Parkinson's disease (PD). Specifically, her program of research is centered on the neuropsychological characterization and rehabilitation of individuals with PD and is therefore, well-suited to carry out the proposed activities of this project. Dr. Schiehser will serve as the PI of this study and within this role, she will oversee all aspects of the project including, but not limited to, coordinating the recruitment, neuropsychological testing, and data management of all participants. Dr. Schiehser will also be responsible for the training and supervision of the study coordinator and research assistants who will be conducting the scheduling and testing. In addition, she will conduct weekly lab meetings devoted to the issues that may arise in this study.

Lin Liu, PhD, Co-Investigator.
Dr. Liu is a Statistician at the VASDHS and an Assistant Professor within the Department of Family and Preventive Medicine at UCSD. She is an experienced Biostatistician with expertise in both observational and clinical trial studies. Her methodological research expertise include longitudinal data analysis, order restricted statistical inference, and prognostic modeling. Dr. Liu will provide methodological and statistical analytical consultation and oversight for this study, including post-data collection manuscript preparation.

Vincent Filoteo, PhD, Co-Investigator.
Dr. Filoteo is a Staff Psychologist at the VA San Diego and a Professor of Psychiatry / Neuropsychology Section Chief at UCSD. Dr. Filoteo has over 20 years of experience in conducting research in demented and nondemented PD patients. He has been the recipient of two federally-funded grants examining (1) the cross-sectional deficits of PD patients on

experimental neuropsychological measures that focused on learning and memory, and (2) novel predictors of cognitive, motor, and psychological decline in PD patients. Dr. Filoteo will lend his expertise regarding PD neuropsychological assessment to this study as well as provide PD participant referrals.

Julie Wetherell, PhD, Co-Investigator.
Dr. Wetherell is a as a VA clinical psychologist and Professor of Psychiatry at UCSD. She is a leading expert in anxiety disorders and the application of MBSR in randomized controlled trials, particularly with older populations. She has been conducting research on MBSR with older adults with anxiety, depression, and cognitive concerns for several years. Dr. Wetherell will provide ongoing consultation on issues involved in conducting MBSR research with older adults and treatment outcome research methodology. She will also contribute to the interpretation and writing of scientific publications resulting from the trial.

Dr. Ece Bayram is a WOC'd research assocaite and Postdoctoral Research Fellow at UCSD Department of Neurosciences. She will aid in the administration of the UPDRS Part III with this study. She is authorized to obtain consent for subjects of VA research.

Nicole Whiteley is the study coordinator and study contact in the lab. She will manage the study and be responsible for subject tracking, scheduling, and also aid in subject recruitment. She is authorized to obtain consent for subjects of VA research and administer neuropsychological tests involved with the study.

Angelie Cabrera Tuazon is a research assistant in the lab and will also aid in subject recruitment. She is authorized to obtain consent for subjects of VA research and administer neuropsychological tests involved with the study.

Kaylee Bashor is a research assistant in the lab and will also aid in subject recruitment. She is authorized to obtain consent for subjects of VA research and administer neuropsychological tests involved with the study

Tiana McMann is a research assistant in the lab and will also aid in subject recruitment. She is authorized to obtain consent for subjects of VA research and administer neuropsychological tests involved with the study

Section 22 - Bibliography

22) List relevant articles that the IRB can use to provide necessary background for the protocol. Do not include an extensive NIH-grant-style bibliography. (Up to 5 recommended, but use more if needed to support the protocol or citations above.)

1. U.S. Department of Veterans Affairs. Research on Parkinson's Disease [online]. Retrieved from: https://www.research.va.gov/topics/parkinsons.cfm on June 1, 2018.

2. Wade DT, Gage H, Owen C, Trend P, Grossmith C, Kaye J. Multidisciplinary rehabilitation for people with Parkinson's disease: a randomised controlled study. J Neurol Neurosurg Psychiatry 2003;74:158-162.

3. Karlsen KH, Tandberg E, Arsland D, Larsen JP. Health related quality of life in Parkinson's disease: a prospective longitudinal study. J Neurol Neurosurg Psychiatry 2000;69:584-589.

4. Schiehser DM, Han SD, Lessig S, Song DD, Zizak V, Filoteo JV. Predictors of health status in nondepressed and nondemented individuals with Parkinson's disease. Arch Clin Neuropsychol 2009;24:699-709.

5. Prakash KM, Nadkarni NV, Lye WK, Yong MH, Tan EK. The impact of non-motor symptoms on the quality of life of Parkinson's disease patients: a longitudinal study. Eur J Neurol 2016;23:854-860.

6. Fountain-Zaragoza S, Prakash RS. Mindfulness Training for Healthy Aging: Impact on Attention, Well-Being, and Inflammation. Front Aging Neurosci 2017;9:11.

7. Lenze EJ, Hickman S, Hershey T, et al. Mindfulness-based stress reduction for older adults with worry symptoms and co-occurring cognitive dysfunction. Int J Geriatr Psychiatry 2014;29: 991-1000.

8. Cash TV, Ekouevi VS, Kilbourn C, & Lageman SK. Pilot study of a mindfulness-based group

intervention for individuals with Parkinson's disease and their caregivers. Mindfulness 2016;7: 361-371.

9. Dissanayaka NN, Idu Jion F, Pachana NA, et al. Mindfulness for Motor and Nonmotor Dysfunctions in Parkinson's Disease. Parkinsons Dis 2016;2016:7109052.

Section 23 - Sponsors and Collaborators

23) Clarify any industry financial or other support (e.g., NIH funds the study or Company X provides the assay kits). Identify non-VA Research collaborators and their role in this protocol, including whether or not they have access to subjects or identified data.

Irene Litvan, M.D. (Consultant) is a Professor in the Department of Neurosciences, and the Director of the Movement Disorders Program at UCSD, a board-certified neurologist with a specialization in Parkinson's disease, as well as a Professor and Tasch Endowed Chair in Parkinson's disease Research at UCSD. Dr. Litvan is a world-renowned expert in Parkinson's disease. She will be involved in patient referral and confirmation of diagnosis to meet study criteria on non-Veteran participants through ROI and provide consultation on issues regarding motor and non-motor symptoms in PD.

Steven Hickman, PhD, (consultant) is the Founder and Director of the UCSD Center for Mindfulness and an Associate Professor of Family and Preventative Medicine. Dr. Hickman is a licensed clinical psychologist and leading expert and world-renowned trainer in Mindfulness interventions. Dr. Hickman was trained in MBSR at UMass by Jon Kabat-Zinn and is a Certified MBSR Teacher and a trainer of teachers of MBSR worldwide, having taught MBSR for over 17 years. He will provide consultation on the implementation of the Mindfulness intervention (MBSR) protocol. In addition, Dr. Hickman will provide interpretation of results specific to mindfulness acquisition and psychological outcomes.

In the submission form, upload a copy of the grant, subaward, CRADA, etc. as appliable to the study.

Section 27 - Privacy, Confidentiality, and Information Security

27a) Provide a brief description of how participant privacy and confidentiality will be protected in this study. Describe the circumstance under which it may be possible for a research team member to identify subjects and any related protections or assurances to prohibit or avoid identification. Describe how the number of people with access to identifiers for research purposes is limited in order to protect a participant's privacy.

Participant identity will be coded immediately upon entry into the study, and neither the participants' names nor any identifying information will be present in the data set. Data collected in other areas (testing rooms) will be brought to the lab and locked away each night. Only approved study personnel will have access to this information.

Hard copy PHI is collected and will be stored in a locked filing cabinet in the PI's lab space. All electronic PHI collected will be stored on a VA computer within the secure VA network. PHI will be stored separately from coded data. Only research staff listed on the protocol will have access to the identifiers and data.

In the groups, which are audio recorded, subjects are asked to call each other only by their first name, to help avoid confidentiality breach.

In the event of a real or suspected breach of security, the VA Police, Information Security Officer, and the Privacy Officer will be notified.

27.b) Entry of a CPRS Research Informed Consent Note is required when subjects will be admitted as inpatients or treated as an outpatients for research *and* the study involves research medical care or may affect medical care.

- ***If a Research consent Note is required, then a Research Progress Note should also be entered for each procedure or intervention.***

- ***Scanning the Consent and HIPAA Authorization into CPRS is not required. Linking the Consent to the Research Informed Consent Note may be permitted and can be useful for trials involving the Research Pharmacy or when research will be performed in conjunction with clinical procedures.***
- ***For Non-Veterans, if Research Informed Consent Notes are entered, then the NOPP Acknowledgment must be scanned into the record. Otherwise a copy of the signed NOPP must be retained with the Investigator's research records and a copy sent to the Privacy Officer; see the ? Help for more information.***

27.b1) Is entry of CPRS notes required based on the above criteria?

- ○ CPRS notes are needed for ALL subjects
- ◉ CPRS notes are needed for SOME subjects
- ○ CPRS notes are NOT needed for any subjects

Identify for which group or groups CPRS records will be entered and to which groups this requirement does not apply.

CPRS will be entered for subjects who pass eligibility screening, are enrolled, and attend at least one group session. CPRS records will not be entered for those who fail eligibility screening after signing informed consent or who drop out prior to groups.

27c) Select the VA Sensitive Information (VASI) use category

- ○ This study does not collect or use any VASI
- ○ This study uses but does not save, collect, copy, or record VASI
- ◉ This study does collect or record VASI

Section 27.1 VA Sensitive Information (VASI)

27.1a) For each type of VASI, indicate all that apply:

Indicate which of the following will be collected/recorded:

- ☑ Protected Health Information (PHI)
- ☑ Names
- ☐ Device identifiers and serial numbers
- ☐ E-mail addresses
- ☐ Medical record numbers
- ☐ URLs (Universal Resource Locator)
- ☑ All elements of dates (except year) or any age over 89
- ☐ Health plan beneficiary numbers
- ☐ IP Addresses (Internet Protocol)
- ☑ Telephone numbers
- ☑ Account numbers
- ☐ Biometric Identifiers including finger and voice print
- ☐ Fax numbers
- ☐ Certificate or license numbers
- ☐ Full face photographic images and comparable images
- ☐ All geographic subdivisions smaller than a state
- ☐ Vehicle ID and serial numbers including license plate numbers
- ☑ Social security numbers or scrambled SSNs (describe below)
- ☐ Other unique identifying number, characteristic, or code (describe below)

27.1a1) Describe why SSN are needed for this study

SSN are needed for subject payment

27.1b) Consent Forms and/or HIPAA Authorization

(•) Yes ( ) No

27.1c) Images with personal identifiers are used for this study (x-rays, MRI images with patient names, record numbers, dates, etc.)?

( ) Yes (•) No

27.1d) Photos with faces or audio video recordings are used for this study.

(•) Yes ( ) No

27.1d1) Identify the device or devices that will be used to take/make the photographs or recordings.

An audio recorder will be used to record group interventions to asses treatment fidelity. We will also be using a video-recorder to tape some of the intervention sessions for future training purposes. We will be using an Olympus 7000 Voice Recorder. We will be using a VA approved video camera to make video recordings.

27.1d2) Identify where images will be stored (e.g., in the medical record, with study hardcopy records, with study electronic VASI records

Audio recording will be transferred to a computer system and assigned group numbers, and will not be individually identifiable. The key relating group numbers to the individuals will be stored separately, protected by strong passwords, and accessible only by approved study personnel.

Video recordings will be uploaded to the VA secure network R drive (in R:\Schiehser) and will only be accessible to the approved study staff through PIV log in. The video recordings will also be on the video camera, in the PI's lab space, in a locked drawer in building #13, separate from the de-identified data files.

27.1e) Biological specimens with identifiers are used for this study.

( ) Yes (•) No

Section 27.2 Data Collection, Tools, and Resources

27.2a) Will any specially obtained software be used?

( ) Yes (•) No

27.2b) Will any mobile devices (laptop, tablet, portable hard-drive, etc.) be used in support of this study?

○ Yes ◉ No

27.2c) Does the study require use of an electronic data capture system?

◉ Yes ○ No

27.2c1) Provide the web address, details regarding their security features, the nature of the data involved, and the research purpose. Also include a description of how VA retains a copy of the data entered into the system.

https://vaww.virec.research.va.gov/REDCap

We will be using HIPAA compliant VA system REDCap. Security features include that the website is accessible only on a VA computer, through the VA network and requires VA Network ID. Data is backed-up nightly and every six hours. Once verified and approved through the VA, staff will access the REDCap database through the aforementioned security features. Research staff listed in the protocol will have access in Redcap. The purpose of using REDCap is that it is designed for human subjects research, allows for secure storage, and provides de-identification features as to not store any PHI.

The entered data will be de-identified and consist of the following variables: health/demographic variables, MDS-UPDRS scores, neuropsychological data and scores, and psychiatric data. The data entered into the systems can be exported by research staff that are listed in the protocol.

27.2d) Will any other web-based applications be used (e.g., for recruitment, completing online questionnaires, or processing data)?

○ Yes ◉ No

27.2e) Will coded data that excludes personal identifiers be used? Coded data excludes *all* HIPAA identifiers (per VHA Handbook 1605.1 Appendix B), including dates

◉ Yes ○ No

27.2e1) Identify where the code key is stored and in what format (electronic, paper).

The code key will be in an electronic and hardcopy format but separate from the coded data

Section 27.3 Data Sharing and Transportation

27.3a) Does this study involve collecting, sharing or transporting any type of data outside of the local VA?

◉ Yes ○ No

27.3b) This study collects VASI outside of VA (i.e., at a non-VA location).

○ Yes ◉ No

27.3c) VASI is transported outside of VA for any purpose other than sharing.

○ Yes ◉ No

27.3d) PHI may be disclosed to monitoring/auditing agencies by HIPAA Authorization. ***Note: The Research Office must be notified when monitors come to audit***

○ Yes ◉ No

27.3e) Data may be shared with collaborators or others in the conduct of this protocol.

◉ Yes ○ No

27.3e1) Describe the data to be shared or disclosed, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data. For PHI and VASI, indicate the authority/ies permitting the sharing or disclosure of data (HIPAA Authorization, Limited Data Set, Data Use Agreement, VA Form 10-5345-Request for and Authorization to Release Health Information., etc.).

De-identified data may be shared to be analyzed with the previously listed collaborators. The de-identified data will not have any code or way to re-identify subjects at any point. This de-identified data will be sent via encrypted email, and while being analyzed, will be stored in a standalone (non-networked), password-protected computer by the collaborators at UCSD. No participant data or identifying data will be collected by the collaborators, and no identifying data will be stored with them.

Section 27.4 Research Record Storage and Retention

For each type of record, indicate whether it is collected for this study

27.4a) Hardcopy records/data (includes paper, pictures, film, etc.)

◉ Yes ○ No

27.4a1) Identify precisely where hardcopy data will be stored to include physical site, building, and room number, etc. For each location identify whether VASI or non-sensitive information is stored at that location. For VASI, identify how the data is secured.

Neuropsychogical tests, administered in a pencil-and-paper format, will be administered and recorded answers, VASI, and non-sensitive information will be stored in the PI's lab space (rooms 330, 332, and/or 306b) in locked cabinets and/or on VA computers in building 13.

27.4a2) Are all of the above locations at VA?

(•) Yes ( ) No

27.4b) Electronic study records (includes computer files, removable disk files, digital files, etc.).

(•) Yes ( ) No

27.4b1) Identify precisely where ***non-sensitive*** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

Location of Electronic non-sensitive records/data: \\R01SDCHSM02.R01.MED.VA.GOV\Research\Schiehser

Audio recordings of the intervention meetings will be transerred to the VA computer R drive so that investigators may assess treatment fidelity, and all audio files will be destroyed at the end of the study. De-identified, hard copy, audio tapes will be given to Dr. Hickman (collaborator) and will be picked up once he is done assessing the recordings. The de-identified data given to Dr. Hickman will not contain any codes and have no way of being re-identified at any point.

The data stored on the R-Drive can only be accessed through a VA computer and study staff who are on the protocol will have specific access to the PI's research folder. Non-sensitive electronic data include the following: health variables, MDS-UPDRS scores, neuropsychological scores, cognitive status, and psychiatric data.

27.4b2) Identify precisely where ***VASI*** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

If no VASI is collected or recorded for this study, simply indicate that the "Study does not collect or record VASI".

Location of Electronic VASI: \\R01SDCHSM02.R01.MED.VA.GOV\Research\Schiehser

VASI will be stored on the secure VA computer R:\ drive (local network storage behind VA firewall) which requires PIV access. The folders will be backed-up by VASDHS IT service. Only study staff who are on the protocol will have access to the PI's research folder.

VASI including name, contact information, code key, appointment dates, and last four of SSN will be stored.

27.4b3) Are any of the locations described in 27.4b outside of the VA Secure Network? *Note: this includes storage on a computer local hard drive.*

( ) Yes (•) No

27.4c) Record Retention - VHA requires compliance with Records Control Schedule (RCS-10) for retention of electronic and hard copy records. Following study closure, these temporary records must be retained for six years and then destroyed. Longer retention may be permitted if required by other Federal regulations or requirements. Will RCS-10 requirements be followed (i.e., 6-year retention)?

(•) I will adhere to VHA Records Control Schedule-10 requirements
( ) I request an exception to RCS-10 requirements

Section 27.5 Additional Privacy or Information Security Details

Provide any other privacy or information security details here.

n/a

Section 27.6 Attestations

In the event of real or suspected breach of security, the Information Security Officer, Privacy Officer, VA Police (if appropriate), and the individual's supervisor will be notified within one hour of learning of the event.

(•) Agree ( ) Disagree

Study staff will be up to date on any required VHA Privacy Policy and Information Security training or they will not be allowed access to VA Sensitive Information.

(•) Agree ( ) Disagree

Access to research sensitive information, if any, will be removed when study personnel are no longer part of the research team.

(•) Agree ( ) Disagree

At least one copy of all study records (whether sensitive or non-sensitive) will be retained under VA control and only destroyed in compliance with the approved Records Control Schedule

(•) Agree ( ) Disagree

The VA retains ownership of the research data. Should the investigator leave the VA, custody of the research records will be assigned to another investigator and the Research Service notified in writing, or custody of the research records will be transferred to the Research Service.

(•) Agree ( ) Disagree

Section 28 - Protocol Association to New or Existing Project

28) Is this a new R&D Project? Before you go on to complete the *Initial Review Submission Form* (which is used for attachments), please address the association of this Protocol to an R&D Committee Project. This Protocol may represent a new R&D Project, or it may be an additional Protocol under an existing R&D Project (such as when a single grant supports multiple Protocols). Will this Protocol be submitted to the R&D Committee as a new Project?

(•) Yes ( ) No

The Protocol Application is now complete for a Protocol that will also be a new R&D Committee Project.

Next you will go on to the Initial Review Submission Form which is used to package up the Protocol Application and any needed attachments and submit them to the IRB.

Click on *Save and Continue*