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Baylor College of Medicine

HOUSTON VA HEALTH SERVICES
RESEARCH AND DEVELOPMENT
CENTER OF EXCELLENCE
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March 16, 2011

Parkinson's Study Group
1351 Mt. Hope Avenue, Suite 223
Rochester, New York, 14620

Re: Parkinson's Study Group Mentored Clinical Research Award

Dear Committee Members,

I am pleased to submit my application for the PSG Mentored Clinical Research Award. The proposed project "Behavioral Treatments for Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study" is an important piece of preparation for further treatment outcomes studies for management of anxiety in individuals with Parkinson's disease (PD). The joint affiliation with Baylor College of Medicine and the Michael E. DeBakey Veteran Affairs Medical Center allow access to infrastructure needed to develop as a researcher in health care settings and provides collaboration with expertise at BCM's Parkinson's Disease Center and Movement Disorder Clinic and the Parkinson's Disease Research and Education Clinical Center.

Under the mentorship of Dr. Laura Marsh, with co-mentorship from Dr. Melinda Stanley, this pilot project will provide the preliminary work and experience necessary to begin to evaluate cognitive behavior treatments for anxiety in individuals with PD. Dr. Marsh has unique expertise in neuropsychiatric aspects in PD and Dr. Stanley is an established investigator in cognitive-behavior treatment studies for late life anxiety. This proposal provides me with the opportunity to develop expertise in the psychiatric care of individuals with PD and broaden my knowledge of clinical outcomes studies. The experiences gained from this proposal would help me to transition to an independent researcher and ultimately contribute to defining evidence based management of anxiety in PD. Thank you for your consideration.

Sincerely,

Jessica S. Calleo, Ph.D.
Assistant Professor of Psychiatry and Behavioral Sciences,

1351 Mt. Hope Avenue, Suite 223
Rochester, New York, 14620
(585) 275-1642

Application Face Page for PSG Scientific Proposals and Studies

Attachment 1

1. Project Title	Behavioral Treatment of Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study
2. Principal Investigator(s): (Name and Institution)	Jessica Calleo, PhD Baylor College of Medicine
3. Co-Investigator(s): (Name and Institution)	Mentor: Laura Marsh, MD Baylor College of Medicine and Michael E. DeBakey Veteran Affairs Medical Center
4. Is this a resubmission? (yes/no) Please provide appropriate documentation as noted in the RFP.	No
5. If PSG data-mining project, has this question been addressed in PSG populations before? (yes/no)	No
6. If yes, explain how/why your proposal is different from what was previously done	N/A
7. Note if abbreviated NIH application is attached (yes/no)	Yes
8. Note if protocol synopsis is attached (yes/no)	Yes
9. If grant application is anticipated, please list name of granting organization or entity.	N/A
10. List proposed grant submission due date	3/25/2011
11. Is collaboration with a PSG credentialed Biostatistics Center requested? (Required if a clinical trial) If yes, please indicate resources needed.	No
12. If yes to question #11 above, are funds available to support a Biostatistics Center's efforts (including during grant application process)?	N/A

Application Face Page (Continued)

13. Is collaboration with a PSG credentialed Coordination Center requested? (Required if a clinical trial) If yes, please indicate resources needed (i.e. data requested for access).	No
14. If yes to question #13 above, are funds available to support a Coordination Center's efforts (including during grant application process)?	N/A
15. Estimated project budget	$55,725
16. Source of Funding. Note if funding is requested or received. **Note: For Mentored Clinical Research Award applicants, if you are submitting to another funding source, please list name of granting organization or entity and type of grant.**	Funding Requested for Mentored Clinical Research Award.
17. Identify any participating "for profit" company/partnership	None
18. Identify any participating "not for profit" company/ partner-ship, including lead institution for project	None
Include any additional background or other information that may help in the review process.	Co-Mentor: Melinda Stanley, PhD Baylor College of Medicine and Michael E. DeBakey Veteran Affairs Medical Center
For studies not intended as observational: An abbreviated NIH format proposal (max=5 pages) to include the specific aims of the study, background, preliminary studies, research design and methods, plus references, and a protocol synopsis and schedule of activities, is required.	Yes.

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Research Plan

Objective: The proposed study will pilot an evidence-based cognitive-behavioral therapy (CBT) intervention for anxiety for individuals with Parkinson's disease (PD). CBT is recognized as an effective psychotherapeutic treatment for anxiety in the general population. However, despite the frequent occurrence of anxiety in PD and its burden to patients, caregivers, and providers, there are no evidence-based studies of treatments for anxiety in PD. Accordingly, this study will provide the preliminary data necessary for designing a future randomized clinical trial (RCT), including information on the feasibility and acceptability of a CBT intervention for patients with clinically significant anxiety and PD, their caregivers, and care providers.

Specific Aims:

Aim 1: Conduct a controlled pilot study of a CBT treatment package for individuals with PD who have clinically significant anxiety in order to:

a. Estimate effect sizes of CBT for anxiety relative to enhanced usual care in 20 patients on outcome measures of anxiety severity and quality of life (QOL).
b. Examine feasibility and acceptability of the treatment.
c. Obtain feedback on the content and delivery of the CBT package from patients, caregivers, therapists, health-care providers and an expert panel.

Aim 2. Refine the components of the CBT treatment package used in Aim 1.

Background & Significance: PD is a neurodegenerative disease characterized by the classic motor features of bradykinesia, rigidity, and tremor; but altered motor function represents only part of the disabling features of this disease. Of those with PD, up to 50% experience clinically significant anxiety.[1] Anxiety symptoms predict lower QOL in PD patients over and above motor symptoms[2] and are associated with impaired activities of daily living, pain, and communication difficulties.[3,4] Despite this prevalence and reductions in health-related QOL, anxiety often remains unrecognized or inadequately treated.[5] Clinical management of anxiety in PD is complicated by the overlap of symptoms in anxiety disorders (e.g., restlessness, sleep disturbance, muscle tension, racing heart, low energy), PD and other common physical and psychiatric illnesses. Even when anxiety is recognized by providers and patients, no evidence-based treatments are available that provides sufficient support for anxiety management in PD. There are no reported clinical trials of medications or behavioral management for anxiety in PD. Pharmacologic interventions for anxiety have unknown effectiveness and side-effects, which can limit their use. However, published case studies suggest successful adaptation of CBT skills for anxiety in PD.[6,7] In addition, a few pilot studies and 1 larger RCT have yielded positive outcomes for CBT treatment for depression in PD.[8] Because depression and anxiety frequently occur in patients with PD, one investigator recently reported the successful incorporation of anxiety management skills into the CBT intervention.[8] While this provides evidence that anxiety, at least within the context of depression, responds to CBT, the effectiveness of CBT for primary anxiety disorders and anxiety without depression in PD is unknown. Versions of CBT studied in prior pilot studies are limited in both content and delivery to meet needs of patients with anxiety and PD. See Table 1. Given the high rates and negative impact of anxiety in PD, a treatment that directly addresses these symptoms is essential since it is not a focus of current CBT treatments. CBT-based protocols appear promising for the management of anxiety in PD due to their established benefits in older and younger adults[9,10] and ability to incorporate and tailor elements of the CBT package to meet the needs of patients with PD. CBT is one of the most well

researched and effective approaches for many psychiatric disorders, psychosocial problems (marital problems, school refusal) and health behaviors (weight loss, medication management, smoking). It is based on the assumption that unhealthy (or maladaptive) behaviors are learned and can be modified using principles of learning theory. The CBT model is ideal for research in a medical setting due to the focus on current behaviors, active role of the therapist, and the setting of measurable treatment goals. A distinct advantage of CBT is that it permits flexibility, while at the same time providing a standardized intervention method that can be replicated by providers. Examples of flexible standardized interventions for late life anxiety are provided in preliminary data section below. The components of the CBT package can be adapted to include self-management skills, such as education on health, nutrition, and exercise and strategies to manage medications, improve sleep, cope with physical symptoms, and improve communication with providers. These types of tools as part of the CBT package for PD-anxiety would improve the overlapping symptoms and aggravation of motor symptoms by anxiety. CBT and self-management skills has also been effectively integrated to improve the QOL of patients with chronic disease but has not been studied with patients with PD[11]. Thus, the integrated treatment can also address caregiver stress[12] and cognitive dysfunction in PD by including caregivers in the intervention and modifying the treatment to accommodate the patient's cognitive deficits.

Table 1.Prior CBT pilot studies and case series for depression in PD with at least 5 patients

Study	**N**	**Caregiver Participation**	**Telephone Option**	**Anxiety Skills**	**Depression Skills**	**PD Self-Management**
Farabough [13]	8				✓	
Dobkin et al.[14]	15	✓			✓	
Cole[14]	5				✓	
Dobkin et al.[8]	80	✓		✓	✓	
Veazey et al.[7]	14		✓	✓	✓	
Proposal		✓	✓	✓	✓	✓

The proposed treatment package addresses the limitations of previous treatments by integrating components from other successful CBT and self-management protocols for late- life populations. Proposed adaptations will allow the treatment package to address anxiety with and without depressive symptoms, provide PD-specific self-management skills, offer structure and tools to increase successful implementation of skills in patients with varying cognitive skills, provide telephone delivery of treatment, and direct attention to stress management in caregivers.

Preliminary Data:

CBT for Anxiety in Older Medical Patients: Preliminary studies and an ongoing clinical trial (R01-MH53932; PI: Stanley) support the potential utility of a flexible CBT package for anxiety in older medical patients. Dr. Calleo has worked for 3 years on this project in various capacities, including as research coordinator and clinician. She has received an NIH supplement to this R01 to examine the mediating and moderating effects of executive functioning on treatment outcomes. The CBT protocol, designed for the treatment of generalized anxiety disorder in older medical patients treated in primary care, is flexible in delivery and content.[16] This modular-based treatment consists of skills provided to everyone (core modules) and optional skills (elective modules) chosen based on patient symptoms and preference. The procedures also include optional telephone delivery of treatment and integration with the medical clinics by working with

providers to identify potentially eligible patients and sustained communication during the course of the patient's participation in the study. Telephone sessions decrease the burden of travel due to medical, physical and financial constraints. In the pilot study for this protocol, 65% of included patients elected to have at least 1 session by telephone. Patients receiving the modular CBT reported significant decreases in worry and anxiety and high satisfaction with treatment.[17]
Development of CBT Treatment Manual for Anxiety and Depression in PD. The initial development of the treatment manual integrating CBT for anxiety, cognitive impairment, and self-management of PD has recently been funded by the Department of Veterans Affairs (VA) Mental Illness Research and Education Clinical Center (MIRECC) pilot program (PI: Jessica Calleo and Co-Is: Laura Marsh, Melinda Stanley, Michele York and Mark Kunik). The funds contribute to the development of the CBT manual and preliminary testing of the treatment with 5 Veterans with anxiety or depressive symptoms and PD. The inclusion of those with significant anxiety symptoms instead of DSM based anxiety diagnosis is based on the unclear applicability of DSM anxiety criteria in patients with PD, a desire to account for anxiety associated with PD that does not meet full criteria for a DSM disorder (e.g. panic associated with motor symptoms) and in order to meet the ultimate goal to provide a useful intervention to those whose anxiety is interfering and disabling. The patients will be all characterized in terms of a DSM diagnosis and information used to help guide final treatment intervention and methods for future RCT. The additional support from the PSG will allow conduction of a controlled trial that will provide preliminary evidence to estimate enrollment and effect sizes and evaluate feasibility and acceptance of the treatment varied clinics. Such information is critical to develop a future application for a larger RCT examining the effectiveness of CBT for anxiety in patients with PD.

Methods: Recruitment: Twenty patients with idiopathic PD and significant anxiety will be recruited from the Parkinson's Disease Center and Movement Disorder Clinic (PDCMDC) at Baylor College of Medicine and the Parkinson's Disease Research and Education Center (PADRECC) at the Michael E. DeBakey VA Medical Center by provider and self-referrals. Recruitment procedures will include 1) weekly meetings with PDCMDC providers and clinic staff to review potential patient referrals and 2) informational brochures, flyers and letters to facilitate self-referrals.
Inclusion/Exclusion criteria: Patients will be included if they (1) have a confirmed diagnosis of idiopathic PD based on UK Brain Bank criteria by a movement disorder specialist, and (2) have significant anxiety, as indicated by a score ≥ 6 on the Hospital Anxiety and Depression Scale[17] (HADS) anxiety subscale. Patients will be excluded if they have significant cognitive dysfunction or possible dementia, as defined by the Montreal Cognitive Assessment[18] (MoCA < 23), or if they have conditions that threaten their immediate safety, including active suicidal intent; current uncontrolled, disruptive psychosis; bipolar and/or substance-abuse disorders; or impulse-control disorders within the past month, as assessed by the Structured Diagnostic Interview for the *DSM-IV*[19] (SCID-I/P). Use of psychotropic medications will be allowed, although patients will need to be on stable regimens, defined as having no change in psychotropic medication type or dose in the month prior to baseline assessment. All other co-occurring physical and psychiatric conditions will be assessed but allowed to determine effectiveness and feasibility of the program in clinical care.
Treatment Description: The CBT consists of 8 weekly sessions, each approximately 45 minutes. Information obtained during the initial assessment and first treatment session will guide the counselor to recommend selection of specific content for the following sessions; ultimately,

patient preference determines which skills will be the focus of the treatment. The treatment package will consist of 1) Patient Core Skills (sessions 1 – 2): motivational interviewing, education and awareness of anxiety and PD symptoms and diaphragmatic breathing for relaxation; 2) Patient Self-Management Skills for PD health (sessions 3-5) selected from the following : healthy living (diet, exercise), managing medications, improving sleep, coping with physical symptoms, and improving communication with providers); 3) Patient Elective Skills for Anxiety (sessions 5-7) selected from the following: behavior change and activation, cognitive, and relaxation skills; 3) *Optional Caregiver Stress Management (1 session; caregivers only):* self-management skills for improving the caregiver's own health, relaxation skills and behavior activation; 4) Patient Review and Maintenance of Gains (session 8). Patient self-management and elective skills for anxiety take 1 or 2 sessions, depending on the skill and feedback from the patient and caregiver. Flexibility in the content of the skills or modular-based treatment will allow the patient and counselor to personalize interventions for individual anxiety symptoms. Within all skill sessions, strategies will be implemented that compensate for mild deficits in cognitive functioning. Session structure and presentation will be adapted from previous manuals that target low-income and frail older adults[20] and patients with dementia.[21] Modifications in session structure to aid patients with impairments in memory, attention and executive skills will include the use of patient-specific retrieval cues (e.g., reminder cards, calendars) to improve organization, planning, and retrieval of skills; repeated in-session practice of new material, written summaries, concrete examples and instructions presented verbally and in writing at each meeting; and collateral support to help practice newly learned coping skills. The first treatment session is in-person to increase rapport and discussion of barriers that may be present in telephone communication. The following sessions are provided in-person or by telephone, based on patient preference. Telephone sessions are structured based on lessons learned from ongoing studies (i.e., scheduling appointments, asking patients to follow along on written materials, attention to repeating instructions and writing down practice exercises). Caregivers will have the option of being involved in 2 ways throughout treatment – as a "coach" to facilitate use of new skills by their loved one with PD and as a recipient of stress-management support. The scope of caregiver involvement will vary across patients, based on patient preference. Involved caregivers will be given the opportunity to participate in 1 telephone-based stress-management session and 1 follow-up call scheduled individually during the first 4 weeks of treatment.
Enhanced usual care (EUC): Patients will continue on current treatment regimens provided to them by their healthcare providers. Anxiety and co-occurring depressive symptoms will be monitored monthly. EUC was chosen for the control condition because newly developed interventions typically include an inactive control condition that allows preliminary evaluation of treatment efficacy, controlling for passage of time and repeated evaluations. EUC allows control of naturalistic changes over time without the need to withhold treatment from patients with clinically significant anxiety and is available from their healthcare providers.
Measures: Primary outcomes will assess the severity of patient anxiety, and secondary outcomes will assess QOL, depression severity, satisfaction with the treatment package, and caregiver burden and depression. The selection of screening and assessment measures was guided by the National Institute of Neurological Disorders and Stroke Clinical Data Elements core recommendations for assessing anxiety and depression in PD. Anxiety will be assessed by the Hamilton Anxiety Rating Scale.[22] Depression will be measured by the Geriatric Depression Scale-15 and the Hamilton Depression Scale.[23] QOL for the patient will be assessed by the Parkinson's Disease Questionnaire-8[24] (PDQ-8). Satisfaction with CBT will be assessed with the

Client Satisfaction Questionnaire[25] (CSQ) and an open-ended Exit Interview designed to gather feedback on treatment procedures and content, completed by both patients and participating caregivers. If participating, caregivers will complete a caregiver burden inventory,[26] which assesses subjective and objective aspects of caregiver life, and the Patient Health Questionnaire-9,[27] a measure of depression severity in the general population.

Procedures: Following initial contact, all interested will schedule consent and screening appointments. Interested patients will be queried as to whether they would like a caregiver to attend and potentially participate in the study with them. If a caregiver is identified, he/she will also attend the consent and screening appointment. Only patients who complete the informed consents and screen positive on the HADS will be asked to complete the remainder of screening assessments (MOCA, SCID-I/P). After we have determined inclusion status and patients have completed the measures noted above at baseline, we will assign them to receive either the CBT treatment or enhanced usual care. They will complete the measures again at 3 months (post-treatment), and 4 months (1-month follow-up). All measures will be administered via the telephone by a trained independent evaluator, someone who is not involved in the patient's care. A Master's-level research assistant working under the PI's supervision will provide all treatment, and all sessions will be recorded for review by Drs. Calleo or Stanley. Case summaries will be prepared for review by mentors, Drs. Stanley and Marsh, at monthly meetings. Patients, caregivers, and PDCMDC and PADRECC providers will be queried regarding strengths and weaknesses of the treatment package.

Consultants: In addition to the co-mentors, a geropsychiatrist with significant expertise in the treatment of dementia, collaborative-care models, and conduct of mental health services research, Dr. Mark Kunik, and a neuropsychologist and section head of neuropsychology at Baylor College of Medicine will provide informal feedback during the study on recruitment, procedures and study implementation during monthly meetings and email.

Analysis. The number and percentage of patients referred who meet inclusion criteria, consent to participate and complete treatment, and the prevalence of specific anxiety disorders will be determined. Outcomes will be examined at both the individual and aggregate level, with effect sizes calculated for each interval. Inferential statistics will be calculated to examine change scores. Patient and treatment characteristics and feedback from patients, caregivers, clinicians, and consultants will be used to modify the treatment package to improve acceptability and outcomes. Dr. Bush will consult with the outcome analysis and plan for future projects.

Table 2. ***Project Timeline***

Months	*Goals*
Aim1: Months 1-3	*Begin meetings with mentors and consultants, collect measures, hire and train research assistant and independent evaluators. Establish recruitment methods.*
Aim 1: Months 4-11	*Recruit and treat 10 CBT and 10 EUC patients. Obtain input from patients, caregivers, therapists, and supervisors. Hold ongoing meetings with mentors and consultants.*
Aim 2: Month 10-11	*Summarize information from patients, caregivers, providers and expert panel. Analyze and present results. Create final version of treatment package. Apply for next grant.*
Aim 2: Month 12	*Create final version of treatment package and work on next grant.*

Human Subjects

Potential Risks

The assessment and treatment procedures may cause some temporary mild increase in worry or related symptoms (e.g., anxiety, depression). Any such increases, however, are expected to be temporary. In addition, all patients will have the opportunity to terminate the assessment or therapy at any time. Patients assigned to enhanced usual care may experience increases in anxiety during that time. Other limitations to confidentiality include situations wherein the patient poses a serious danger to self or others, a medical emergency occurs, or there is cause to believe that a child, older person, or disabled person is being abused, neglected, or exploited. These exceptions to confidentiality are listed on the consent form. Consent forms are filed in a locked area, apart from all coded study data. Data are coded by study number, without identifying information, and information linking study number with patient identity is kept in a separate locked file. When study results are published, they will be anonymous.

Potential Benefits of Proposed Research to Human Subjects and Others

A thorough psychological evaluation at no cost will serve as the basis for a treatment recommendation either within or outside the treatment phase of this study. Benefits of treatment may include reductions in anxiety and associated symptoms (e.g., depression, sleep dysfunction), improved functional status and quality of life, and reduced caregiver distress. Ultimately, this program of research may lead to the establishment of an evidence-based approach to the treatment of anxiety in Parkinson's disease, an area where few efficacy data exist. The potential benefits of treatment relative to enhanced usual care for anxiety outweigh potential risks of increased distress associated with assessment and treatment procedures.

Recruitment and Informed Consent

Patients will be recruited via clinician- and self-referral. To facilitate patient self-referrals, educational brochures will be placed in clinic waiting areas and examination rooms at the Baylor College of Medicine Parkinson's Disease Center and Movement Disorder Clinic. Informational material will include a telephone number for patients to call if they are interested in participation. Research staff will respond to these calls by providing further information about study participation and making an appointment to complete consent and study screening procedures. To facilitate clinician referrals, educational presentations and orientation sessions will be held with physicians and clinic staff in each site to explain the project and its potential benefits for patients, caregivers, and staff. Research staff also will attend regular team meetings and communicate with clinic staff on a regular basis via electronic mail to remind them about the study, facilitate continued patient referrals, and provide progress reports for included patients. Ongoing evaluation of recruitment procedures will occur during monthly research team meetings and through formal and informal contact with mentors and consultants. All patients who express interest will be scheduled for a consent appointment at the clinic. If the patients are interested in a caregiver being present, a request will be made that the caregiver also attends the consent meeting. During the meeting, a study overview will be provided and written informed consent will be obtained. If an initial combined meeting is not possible, the two consent procedures will be conducted separately.

Protection Against Risk.

Patients at high risk for adverse outcomes (e.g., those with active suicidal intent, current psychosis or bipolar disorder, substance abuse within the past month) will be excluded. Clinicians and IEs will be trained to cope with anxiety experienced during consent, assessment, and treatment procedures. Patients who do not meet study inclusion criteria will be provided

with alternative referrals. If any patient shows evidence of the need for immediate treatment (e.g., active psychotic symptoms or suicidal intent) at any time during the screening and evaluation process, the PI and the patient's clinic provider will be notified, and the patient will be referred for immediate psychiatric assistance following standard operating procedures for the clinic. If patients experience significant worsening of symptoms at the 3- or 4-month assessments (20% worsening of anxiety or depressive symptoms), the clinical supervisor and the patient's provider will be notified and the patient referred for immediate psychiatric care. Patients assigned to EUC will receive monthly telephone calls to assess the need for immediate psychiatric care.

References

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Budget Justification

Personnel:

Jessica Calleo, PhD (Principal Investigator): My role as principal investigator will be as supervisor of clinicians participating in the project. I will also oversee all administrative and scientific aspects of proposal and collaborate with mentors and recruit, treat participants in pilot study and create final intervention manual. I will also collaborate with other investigators in the statistical analyses of data, preparation of scientific reports and subsequent grant proposal. Dr. Calleo plans to commit 20% effort to this project but the time commitment to this project is part of her research time commitment to the NIH diversity supplement since this project is compatible with the goals of the diversity supplement. Dr. Calleo's salary is currently covered by the diversity supplement award so she is not requesting salary from this award.

Laura Marsh, MD (Primary mentor, 2% FTE no funds requested). Dr. Marsh is a member of the Parkinson's Study Group, a professor in the Department of Psychiatry and Behavioral Sciences and the Department of Neurology and the Mental Health Care Line executive at the MEDVAMC. Dr. Marsh's research and clinical efforts focus on improving the recognition and treatment of neuropsychiatric aspects of PD. Dr. Marsh will work closely with me to provide supervision of outpatient assessments and care and career development activities.

Melinda Stanley (Co-Mentor, 2% FTE no funds requested). Dr. Stanley is professor and head of the Psychology Division in the Menninger Department of Psychiatry and Behavioral Sciences at BCM. She has a long history of research funding, with a particular focus on developing and testing cognitive- behavioral interventions for older adults with anxiety. She also has significant experience in mentorship of postdoctoral fellows and junior investigators. Weekly supervision will include mentorship on research methods of clinical trials, manuscript collaborations, and other grant-preparation activities.

Research Assistant (50% FTE): One master's level graduate research assistant will be hired to assist with recruitment, administer diagnostic interviews, conduct CBT and EUC. The research assistant will also help with day to day project responsibilities including preparing study material.

Amber Bush Amspoker, PhD (5% FTE): Dr. Amspoker will assist with data analyses and collaborate with other investigators in the preparation of scientific reports and future grant proposals. She has specialization in quantitative methodology, with experience in methodology and statistical analyses for a wide variety of study designs and health outcome projects. She currently serves as co-Investigator for two of Dr. Stanley's ongoing NIMH-funded clinical trials in this area (R01-MH53932; R34-MH078925).

Grant Supplies: A total of $800 per year is requested to cover other supplies needed to support this work (general office supplies, stamps).

Travel: Funds are requested in the amount of $1,800 per trip for Dr. Calleo to annual meeting/scientific conference and $1,800 to travel to course on Movement Disorders.

Other Expenses
Course reimbursement: Funds in the amount of $350 are requested to cover the costs of the Summer Workshop Course on Movement Disorders.

Participant Payments: Participants will be paid $20.00 each for completion of assessments 20 patients and 20 caregivers for 3 assessments; total cost: $2,400.

Independent Evaluators: Request funds for evaluators to complete assessments. It is anticipated hiring two evaluators who will undergo 5 hours ($25/hour) of training and 60 assessments at $25/assessment.

Audio Recorders ($65/item - 2 recorders) and telephone recorder control ($24/item - 2 controls)

Production costs: Intervention manual and training protocol. Including a graphic artist ($80/hour-25 hours: $2000) and color copying costs $500.

Copyright Costs: Obtain the rights to use copyrighted instruments. $500

Computer and Computing Costs: Funds are requested in the amount of $1,500 to cover a computer and $1,396 for computing costs. These costs include charges for Dr. Calleo's usage of the Houston VA Health Service Research and Development Center of Excellence. HSRDC charges are assessed based on the type of HSRDC use by study staff. Dr. Calleo will be provided a local LAN, e-mail service, Internet access, and shared file and print servers, which are supported by HSRCC operations staff. Basic yearly charges per FTE for all personnel cover the pro-rated costs of system administration, maintenance and operations, and upgrades to the LAN and other shared equipment.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Calleo, Jessica Sepulveda (0919)	Assistant Professor, Psychiatry and Behavioral Sciences
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of St. Thomas, Houston	B.A.	05/02	Psychology
University of Houston	Ph.D.	05/08	Clinical Psychology
Baylor College of Medicine	Internship	06/08	Clinical Psychology
Baylor College of Medicine	Postdoctoral Fellowship	06/10	Clinical Research

A. Personal Statement

The goal of this project is to pilot a cognitive behavior therapy treatment for anxiety to increase quality of life among patients with Parkinson's disease and their caregivers. The proposal will facilitate my career development in interventions for neuropsychiatric aspects, clinical trials, and provide preliminary data for future projects to reduce anxiety in patients with PD. In the proposed project, I will oversee all administrative and scientific aspects of proposal and collaborate with mentors and expert consultants to recruit and treat participants in pilot study. I will work with my mentors and expert consultants in the statistical analyses of data, preparation of scientific reports and subsequent grant proposal. My training in clinical psychology and experience in CBT and older adult treatment has prepared me for this role in current pilot proposal. I have worked as a fellow and clinician on the Dr. Stanley's current primary care study (MH53932) and R34, providing CBT for anxious older adults with and without dementia and assisting in project administration, manuscript writing, and supervision of research assistants. I am currently collaborating with Drs. York, Kunik, and Bush on a supplement to the Dr. Stanley's primary care project examining the impact of executive dysfunction on CBT treatment outcomes and with Drs. Stanley, Marsh, York, and Kunik, on a treatment development pilot for anxiety and depression in veterans with PD.

B. Positions and Honors

Positions and Employment

2010- Assistant Professor, Menninger Department of Psychiatry and Behavioral Sciences, Baylor College of Medicine
Clinical Research Psychologist, Michael E. DeBakey Veteran Affairs Medical Center
Investigator, Houston VA Health Services Research and Development Center of Excellence
2008-2010 Post-doctoral Fellow and Research Coordinator, Houston Center for Quality of Care & Utilization Studies, Baylor College of Medicine
2007-2008 Intern, Baylor College of Medicine
2006-2007 Project Coordinator, Peaceful Living Project, Houston Center for Quality of Care & Utilization
2005-2006 Research Clinician, Peaceful Living Project, Houston Center for Quality of Care & Utilization

Other Experience and Professional Memberships

2005- Member, American Psychological Association
2006-2008 Member, Association for Behavioral and Cognitive Therapy
2009- Member, Gerontological Society of American

Honors

2002 Psi Chi (Psychology Honors), University of St. Thomas, Houston, TX
2009 Fellow, 15th Annual Summer Research Institute in Geriatric Psychiatry

C. Selected Peer-reviewed publications

1. **Calleo, J.,** Hart, J., Bjorgvinsson, T., and Stanley, M. (2010). Obsessions and worry beliefs in an inpatient OCD population. *Journal of Anxiety Disorders.* [Epub ahead of print].
2. Paukert, A.L., **Calleo, J**., Kraus-Schuman, C., Snow, L., Wilson, N., Petersen, N.J., Kunik, M.E., & Stanley, M.A. (2010). Peaceful Mind: An open trial of cognitive – behavioral therapy for anxiety in persons with dementia. International Psychogeriatrics 16, 1-10 [Epub ahead of print].
3. **Calleo, J**., Stanley, M., Greisinger, A., Wehmanen, O., Johnson M. and Kunik M. (2009*).* Generalized anxiety disorder in older medical patients: Diagnostic recognition, mental health management and service utilization. *Clinical Psychology in Medical Settings*, 16, 178-185.
4. Weiss, B., **Calleo, J**., Rhoades, H., Novy, D., Kunik, M., Lenze, E., Stanley, M. (2009). The utility of the Generalized Anxiety Disorder Severity Scale (GADSS) with Older Adults in Primary Care. *Depression and Anxiety*, *26*, E10-5
5. **Calleo, J**. & Stanley, M. (2008*).* Anxiety disorders in later life: Differentiated diagnosis and treatment strategies. *Psychiatric Times*, *25*(8).

Relevant Presentations

1. **Calleo, J.,** Stupina, A., Kraus-Shuman, C., Snow, L., Wilson, N., Kunik., M., Peterson, N. and Stanley, M. (2009, November). Examining Worry and Generalized Anxiety Disorder in Patients with Dementia. Poster presented at the Sixty-second Conference of the Gerontological Society of America.
2. **Calleo, J.,** Kraus-Schuman, C., Wilson, N., Khan, M., Cully, J., Kunik, M., Stanley, M. (2009, November). Late Life Minority Recruitment in a Randomized Clinical Trial for Anxiety. Poster presented at the Sixty-second Conference of the Gerontological Society of America.
3. **Calleo, J.**S., Bush, A.L., Cully, J.A., Wilson, N.L., Rhoades, H.M., Novy, D.M., Masozera, N., Williams, S., Horsfield, M., Kunik, M.E., & Stanley, M.A. (2010). Moving toward effectiveness in treatment of late-life GAD in primary care: A pilot study. In A. Paukert (Chair), The Treatment of Anxiety among Older Adults, Symposium presented at the annual meeting of the Association of Behavioral and Cognitive Therapies, San Francisco, CA, November 18-21, 2010.

D. Research Support

R01-MH43932-12S1, Stanley, M.A. (PI) 2010-2012
National Institute of Mental Health
Diversity Supplement to CBT for late-life GAD in primary care: Enhancing outcomes and translational value
Role: **Minority Investigator**

Grant, **Calleo, J** (PI) 2011-2012
Pilot Study Research Program, South Central Mental Illness Research, Education, & Clinical Center (MIRECC)
Increasing Access and Implementation of Behavioral Treatments for Anxiety and Depression in Rural Veterans with Parkinson's disease
Role: **PI**

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Marsh, Laura	Professor, Dept of Psychiatry, Baylor College of Medicine
eRA COMMONS USER NAME (credential, e.g., agency login)	Mental Health Care Line Executive, Michael E. DeBakey
Marshl	VA Medical Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR (s)	FIELD OF STUDY
Oberlin College	B.A.	1981	Psychobiology (Highest Honors)
Ohio State University College of Medicine	M.D.	1986	Medicine (*cum laude)*

A. Personal Statement The goal of this project is to pilot a cognitive behavior therapy treatment anxiety in patients with Parkinson's disease (PD) and their caregivers and to enhance the career development of Dr. Jessica Calleo. In the proposed project, I will mentor to Dr. Calleo on neuropsychiatric aspects of PD, treatment of anxiety in PD, the proposed the treatment procedures, and collaborate in the preparation of scientific reports and future grant proposals. Due to significant expertise in psychiatric assessment and treatment in PD, I will also contribute to providing input regarding assessments of patient and caregivers during the pilot.

A. Positions and Honors

Positions and Employment

1986-1987 Intern, Dept Medicine, Bayview Medical Ctr, Johns Hopkins Univ School Med, Baltimore, MD
1987-1990 Resident, Dept Psychiatry, Johns Hopkins Univ School Med, Baltimore, MD
1990-1991 Senior Staff Fellow, Clinical Brain Disorders Branch, National Institute of Mental Health, Neuropsychiatric Research Hospital at St. Elizabeths, Washington, DC
1991-1993 Postdoctoral Research Fellow, Psychiatric Neuroimaging and Schizophrenia Research, Department of Psychiatry, DVA Med Center/Stanford University, Stanford, CA
1993-1998 Assistant Professor of Psychiatry, Stanford University, School of Medicine, Stanford, CA
1998-1999 Assistant Professor of Psychiatry, Johns Hopkins University School of Medicine, Baltimore, MD
1999-2009 Associate Professor of Psychiatry, Johns Hopkins University School of Medicine, Baltimore, MD
2003-2009 Associate Professor of Neurology, Johns Hopkins University School of Medicine, Baltimore, MD
2009- Adjunct Associate Professor of Psychiatry, Johns Hopkins Univ School of Medicine, Baltimore, MD
2009- Executive Director, Mental Health Care Line, Michael E. DeBakey VA Medical Center, Houston, TX
2009- Professor, Menninger Department of Psychiatry, Baylor College of Medicine, Houston, TX
2009- Professor, Department of Neurology, Baylor College of Medicine, Houston, TX

Other Experience and Professional Memberships

1998-2009 Director, Clinical Core, Johns Hopkins Morris K. Udall Parkinson's Disease Research Center
2005- Member, Scientific Advisory Board, American Parkinson's Disease Association
2007- Member, Scientific Review Committee, Parkinson Study Group
2007-2008 Co-director, Non-Motor Work Group, National Parkinson Foundation
2009- Member, Scientific Advisory Board, National Parkinson Foundation
2009-2010 American Psychiatric Association Representative to the American Academy of Neurology Parkinson's Disease Measure Development Expert Panel

Honors and Awards

1981 Sigma Xi
1981-1982 Thomas J. Watson Fellow
1985 Dorothy Van Ness-Thompson Fdtn Scholarship
1985 Rock Sleyster Memorial Scholarship, American Medical Association;
1985 Alpha Omega Alpha
1988 Biological Research Training Award, Natl Inst Mental Health
1991 Young Investigator Award, Third Intl Congress Schizophrenia Research
1994 Young Investigator Award, Natl Alliance for Research on Schizophrenia and Affective Disorders

1995 Theodore and Vada Stanley Foundation Research Award
1995, 1996 Young Investigator Award, Epilepsy Fdtn America
1995 Junior Faculty Award for Women, Katherine D. McCormick Foundation, Stanford University
1996 – Added Qualifications in Geriatric Psychiatry, American Board of Neurology and Psychiatry
2010 'America's Best Doctors' designation

B. Peer-reviewed publications (selected from >85 articles and chapters)

1. **Marsh L**. Neuropsychiatric aspects of Parkinson's disease. *Psychosomatics*. 2000; 41(1):15-23.
2. **Marsh L**, Lyketsos C, Reich SG. Olanzapine for the treatment of psychosis in patients with Parkinson's disease and dementia. *Psychomatics* 2001; 42;477-481.
3. **Marsh L.** Neuropsychiatric aspects of Parkinson's disease: recent advances. *Curr Psychiatry Rep* 2003; 5:68-76.
4. Reich SG, **Marsh L.** 10 most commonly asked questions about Parkinsons's disease. Psychiatric aspects of Parkinson's disease. *The Neurologist*, 2003; 9(1):50-56.
5. Leroi I, Brandt J, Reich SG, Lyketsos C, Thompson R, **Marsh L**. Randomized placebo-controlled trial of donepezil for cognitive impairment in Parkinson's disease. *Int J Geriatric Psychiatry*, 2004; 19:1-8.
6. **Marsh L**, Williams JR, Rocco M, Grill S, Munro C, Dawson TM. Psychiatric co-morbidities in patients with Parkinson's disease and psychosis. *Neurology* 2004; 63:293-300.
7. Pletnikova O, West N, Lee M, Rudow G, Dawson T, **Marsh L**, Troncoso J. α-synuclein lesions of Lewy body disease are enhanced by Aß deposition. *Neurobiol Aging* 2005; 26(8):1183-1192.
8. **Marsh L**, McDonald WM, Cummings J, Ravina B. Provisional Diagnostic Criteria for Depression in Parkinson's Disease: Report of an NINDS/NIMH Work Group. *Mov Disorders* 2006; 21(2):148-158.
9. Leroi I, Collins D, **Marsh L**. Non-dopaminergic treatment of cognitive impairment and dementia in Parkinson's disease: A critical review. *J Neurol Sci* 2006; 248:104-114.
10. Pontone G, Williams JR, Bassett SS, **Marsh L**. Clinical features of impulse control disorders in Parkinson's disease. *Neurology* 2006; 67(7): 1258-1261
11. Friedman JH, Brown RG, Comella C, Garber CE, Krupp LB, Lou J-S, **Marsh L**, Nail L, Shulman L, Taylor CB, Working Group on Fatigue in Parkinson's Disease. Fatigue in Parkinson's disease: A review. *Mov Disorders* 2007; 22(3):297-308.
12. Ravina B, Marder K, Fernandez H, Friedman J, McDonald W, Murphy D, Aarsland D, Babcock D, Cummings J, Endicott J, Factor S, Galpern W, Lees A, **Marsh L**, Stacy M, Gwinn-Hardy K, Voon V, Goetz C. Diagnostic Criteria for Psychosis in Parkinson's disease: Report of an NINDS/NIMH Work Group. *Mov Disorders* 2007; 22(8): 1061-1068.
13. Ravina B, Camicioli R, Como P, **Marsh L**, Jankovic J, Weintraub D, Elm J. The Recognition and Impact of Depression in Early Parkinson's disease. *Neurology* 2007;69(4):342-347.
14. Richard IH, LaDonna K, Hartman R, Podgorski C, Kurlan R and the **SAD-PD Study Group**. The Patients' Perspective: Results of a survey assessing knowledge about and attitudes toward depression in PD. *Neuropsychiatric Disease and Treatment* 2007: 3(6); 903-906.
15. Fernandez HH, Aarsland D, Fenelon G, Friedman JH, **Marsh L**, Tröster AI, Poewe W, Rascol O, Sampaio C, Stebbins G and Goetz C. Scales to Assess Psychosis in Parkinson's disease: Critique and Recommendations. *Mov Disorders* 2008;23(4):484-500.
16. Leentjens AFG, Dujardin K, **Marsh L**, Martinez-Martin PMM, Richard IH, Starkstein SE, Weintraub D, Poewe W, Rascol O, Sampaio C, Stebbins GT, Goetz CG. Apathy and anhedonia rating scales in Parkinson's disease: critique and recommendations. *Mov Disorders* 2008; 23(14):2004-14.
17. Leentjens AFG, Dujardin K, **Marsh L**, Martinez-Martin PMM, Richard IH, Starkstein SE, Weintraub D, Poewe W, Rascol O, Sampaio C, Stebbins GT, Goetz CG. Anxiety rating scales in Parkinson's disease: critique and recommendations. *Mov Disorders* 2008;23(14):2015-25.
18. **Marsh L**, Biglan K, Gerstenhaber M. Williams JR. Atomoxetine for the treatment of executive dysfunction in Parkinson's disease: A pilot open-label study. *Mov Disorders*. 2009; 24(2): 277-282
19. Williams JR, **Marsh L.** Validity of the Cornell Scale for Depression in Dementia in Parkinson's Disease. *Mov Disorders* 2009 24(3): 433-437.
20. Pontone G, Williams JR, Anderson K, Chase G, Goldstein S, Grill S, Hirsh E, Lehmann S, Little J, Margolis R, Rabins PV, Weiss H, **Marsh L**. Prevalence of anxiety disorder subtypes in patients with Parkinson's Disease. *Mov Disorders*. 2009; 24(9):1333-1338.

21. Ravina B, Elm J, Camicioli R, Como PG, **Marsh L**, Jankovic J, Weintraub D. The Course of Depressive Symptoms in Early Parkinson's Disease. 2009; 24(9):1306-1311.
22. Hollander E, Wang T, Braun A, **Marsh L**. Obsessive-Compulsive Spectrum Disorders- Neurological Considerations: Autism and Parkinson's disease. *Psychiatry Res*, I30:170(1): 43-51. PMID 19815296.
23. Aarsland D, **Marsh L**, Schrag A. Neuropsychiatric symptoms in Parkinson's Disease. *Mov Disord* 2009 Nov 15; 24(13):2175-2186.
24. Friedman JH, Alves G, Hagell P, Marinus J, **Marsh L**, Martinez-Martin P, Goetz CG, Poewe W, Rascol O, Sampaio C, Stebbins G, Schrag A. Fatigue rating scales: Critique and recommendations by the Movement Disorders Society task force on rating scales for Parkinson's disease. *Mov Disorders,* 2010 25(7), 805-822.
25. Weiss HD, Hirsch ES, Swearengin L, Williams JR, **Marsh L**. Detection of Impulse Control Disorders in Parkinson Disease Patients. *The Neurologist*. In press.
26. Okun MS, Siderowf A, Nutt JG, O'Conner GT, Bloem BR, Olmstead EM, Guttman M, Simuni T, Cheng E, Cohen EV, Parashos S, **Marsh L**, Malaty IA, Giladi N, Schmidt P, Oberdorf J. Piloting the NPF data-driven quality improvement initiative. *Parkinsonism Relat Disord* 2010 Sep;16(8):517-21. PMID: 20609611
27. Cheng EM, Tonn S, Swain-Eng R, Factor SA, Weiner WJ, Bever CT Jr; **For the American Academy of Neurology Parkinson Disease Measure Development Panel.** Quality improvement in neurology: AAN Parkinson disease quality measures: Report of the Quality Measurement and Reporting Subcommittee of the American Academy of Neurology. *Neurology.* 2010 Nov 30;75(22):2021-2027. PMID: 21115958.
28. Leentjens AFG, Dujardin K, **Marsh L**, Martinez-Martin P, Richard IH, Starkstein SE. Symptomatology and markers of anxiety disorders in Parkinson's disease: a cross-sectional study. *Mov Disorders* In Press.
29. Pontone GM, Williams JR, Anderson KE, Chase G, Goldstein SR, Grill S, Hirsch ES, Lehmann S, Little JT, Margolis RL, Rabins PV, Weiss HD, **Marsh L**. Anxiety and quality of life in Parkinson's disease. In review.
30. Mack J, Anderson K, Goldstein S, Grill S, Hirsch E, Lehmann S, Little J, Margolis R, Palanci J, Pontone G, Rabins P, Weiss H, Williams J, **Marsh L.** Prevalence of minor psychotic symptoms in a community-based Parkinson's disease sample. *Am J Geriatric Psychiatry.* In press.

C. Research Support

Active

NIMH R01 MH06966 6 Marsh (PI) 05/01/10 – 04/30/11
Methods of Optimal Depression Detection in Parkinson's
To evaluate screening methods to improve depression detection in patients with PD and advise re implementation in clinical neurological practices. Role: PI

Pending NIH U54 NS0657 02 Jinnah (PI, Emory University) 1/1/2011-12/31/2011
The Dystonia Coalition: U54 Multi-Center Consortium
Project 2: Comprehensive rating tools Project Leader: Cynthia Comella, M.D.
Develops clinical assessment tools to evaluate motor and non-motor symptoms and function in cervical dystonia.
Role: Site PI for Project 2

Completed Research Support (Last 3 years)

NIH U54 NS0657 01 Jinnah (PI, Emory University) 9/30/2009-8/31/2014
The Dystonia Coalition: U54 Multi-Center Consortium
Project 2: Comprehensive rating tools Project Leader: Cynthia Comella, M.D.
Develops clinical assessment tools to evaluate motor and non-motor symptoms and function in cervical dystonia.
Role: Consultant Psychiatrist to Project 2

Investigator-Initiated Drug Trial Marsh (PI) 5/1/05– 12/30/09
Forest Research Institute
Memantine for Treatment of Parkinson's Dementia
A pilot study on the efficacy and safety of memantine for dementia in patients with Parkinson's disease.
Role: PI

Michael J. Fox Foundation Leentjens (PI) 11/1/08-12/30/09
The validation of anxiety rating scales in Parkinson's disease

Role: Co-Investigator

NIH P01P50 NS38377 Dawson (PI) 10/01/98 – 08/30/09
A Parkinson's Disease Research Center of Excellence: Clinical Core
To investigate the role of a-synuclein in the pathogenesis of Parkinson's disease in studies and to define the molecular mechanisms of dopaminergic neuronal injury in studies on human and animal models of PD.
Role: PI and Director of the Clinical Core

NINDS R01 NS046487 Richard (PI) 12/01/03 - 11/30/08
Study of Antidepressants in Parkinson's Disease (SAD-PD)
To compare efficacy and tolerability of paroxetine and venlafaxine in Parkinson's disease and depression.
Role: Site PI

NINDS 5R01NS036630-08 Marder (PI) 07/01/07-04/30/09
Genetic Epidemiology of Parkinson's Disease
To define the range of motor and non-motor phenotypic manifestations of parkin mutations and to estimate age specific penetrance of parkin mutations in families of parkin-positive cases ascertained by age at onset, and evaluate differences in age specific penetrance across subgroups defined by allelic state.
Role: Site PI

R01 NS037167 Foroud T (PI) 4/1/2008-3/31/2010
NINDS/ Parkinson Study Group
Parkinson's Disease Collaborative Study of Genetic Linkage" [Working title: "Parkinson's Research: The Organized Genetics Initiative (PROGENI)"]
Role: Site PI

Investigator-Initiated Drug Trial (Eli Lilly) Marsh (PI) 12/1/04 – 6/30/07
Atomoxetine for treatment of executive dysfunction in Parkinson's disease (PD)
A pilot study on the efficacy and safety of atomoxetine for executive dysfunction in patients with PD
Role: PI

R01 HD39822 (NIH-NCE) Bassett (PI) 07/01/01 - 06/30/08
Disability in Parkinson's Disease
To assess motor, cognitive, and emotional function and the related disabilities, longitudinally, in individuals with PD in order to understand how these impairments and psychiatric disorders contribute to disability in PD.
Role: Co-investigator, Study psychiatrist

Industry-Sponsored/Investigator-Initiated Trial Lang/Weintraub (Co-PIs) 04/01/07 – 3/31/09
Boehringer Ingelheim
A Cross-Sectional, Retrospective Screening and Case-Control study examining the frequency of, and Risk Factors Associated with, Impulse Control Disorders in Parkinson's Disease Patients Treated with MIRAPEX (Pramipexole) and Other Anti-Parkinson Agents (DOMINION Study)
Role: Site PI

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Melinda A. Stanley	Professor, Psychiatry and Behavioral Sciences
eRA COMMONS USER NAME mstanley	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Gettysburg College	B.A.	1980	Psychology
Princeton University	M.A.	1982	Social Psychology
Texas Tech University	Ph.D.	1987	Psychology
Western Psychiatric Institute & Clinic	Intern/Post	1986-88	Clinical Psychology

A. Personal Statement

The goal of this project is to pilot a comprehensive cognitive behavior therapy treatment anxiety and to increase quality of life among patients with Parkinson's disease and their caregivers. In the proposed project, I will assist Dr. Calleo in the supervision of clinicians, and provide mentorship regarding the treatment procedures, career development activities and collaborate in the preparation of scientific reports and future grant proposals. I have considerable expertise and a long history of external support in treatment development and clinical trials of cognitive behavioral interventions for late-life anxiety. My colleagues and I have had continuous NIMH support in this area for 14 years (R01-MH53932; yrs 1-14), with studies addressing the effects of CBT for late-life GAD in academic clinical settings (Stanley et al., 2003) and primary care (Stanley et al., 2009; MH53932 ongoing), as well as the development and pilot testing of a model of CBT tailored to meet the needs of older adults with anxiety and dementia (R34-MH078925). Dr. Calleo worked for the past 2 years as a post-doctoral fellow on both of these projects, and she is now the recipient of a diversity supplement to R01 MH53932 that examines the impact of executive dysfunction on outcomes following CBT for late-life GAD.

B. Positions and Honors

Professional Experience

2004-Present Professor; Menninger Department of Psychiatry and Behavioral Sciences; Baylor College of Medicine
Mental Health Services Researcher; Houston Center for Quality of Care & Utilization Studies; Michael E. DeBakey Veterans Affairs Medical Center
Site Leader; South Central Mental Illness Research, Education and Clinical Center

1999-2004 Professor; Department of Psychiatry and Behavioral Sciences; University of Texas - Houston Medical School

1994-1999 Associate Professor; Department of Psychiatry and Behavioral Sciences; University of Texas – Houston Medical School

1988-1994 Assistant Professor; Department of Psychiatry and Behavioral Sciences; University of Texas - Houston Medical School

Licensure

1989-Present Licensed Psychologist, State of Texas, #3731

Honors

2009 Best Publication by a Senior Investigator, Excellence in Research Education Award, South Central MIRECC Department of Veterans Affairs

2008 Excellence in Research Award, South Central MIRECC, Department of Veterans Affairs

2008-2009 Member, Intervention Committee for Disorders Related to Schizophrenia, Late Life, or Personality, NIMH

2003-2005 Reviewer, Intervention Research Review Committee, NIMH

2000 Fellow, Division 12 (Clinical Psychology), American Psychological Association

1998,1997 Special Review Panels, SAMHSA, NIMH

1990,1992,1993 Dean's Teaching Excellence Award, University of Texas - Houston, Medical School
1980 Summa Cum Laude Graduate, Salutatorian, Gettysburg College
1979 Phi Beta Kappa, Gettysburg College

C. Selected peer-reviewed publications

Most relevant to the current application

Bradford, A., Cully, J.A., Rhoades, H., Kunik, M., Kraus-Schuman, C., Wilson, N., **& Stanley, M**. (in press) Early response and long-term outcome of psychotherapy for generalized anxiety disorder in older adults. American Journal of Geriatric Psychiatry.

Robinson, C.M., Paukert, A., Kraus-Schuman, C.A., Snow, L., Kunik, M.E., Wilson, N.L., Teri, L., & **Stanley, M.A.** (in press). The involvement of multiple caregivers in cognitive behavior therapy for anxiety in persons with dementia. Aging and Mental Health.

Cully, J.A., **Stanley, M.A**., Dewsal, A., Hanania, N.A., Phillips, L.L., & Kunik, M.E. (2010). Cognitive-behavioral therapy for chronic pulmonary conditions: Moving beyond mental health outcomes. The Primary Care Companion. Prim Care Companion J Clin Psychiatry, 12 (4):e1-e6

Paukert, A.L., Calleo, J., Kraus-Schuman, C., Snow, L., Wilson, N., Petersen, N.J., Kunik, M.E., & **Stanley, M.A.** (2010). Peaceful Mind: An open trial of cognitive – behavioral therapy for anxiety in persons with dementia. International Psychogeriatrics, Sept; 22(6): 1012-21 PMID: 20550745

Wolitzky-Taylor, K.B., Castriotta, N., Lenze, E.J., Stanley, M.A., Craske, M.G. (2010). Anxiety disorders in older adults: A comprehensive review. Depression and Anxiety, February, 27(2):190-211. PMID: 20099273

Brenes GA, McCall WV, Williamson JD, **Stanley, MA.** (2010). Feasibility and acceptability of bibliotherapy and telephone sessions for the treatment of late life anxiety disorders. The Clinical Gerontologist, January, 33:62-68.

Cully, J.A., Paukert, A., Falco, J., & **Stanley, M.A.** (2009). Cognitive-behavioral therapy: Innovations for cardiopulmonary patients with depression and anxiety. Cognitive and Behavioral Practice, 16:394-407.

Stanley, M.A., Wilson, N., Novy, D.M., Rhoades, H., Wagener, P., Greisinger, A.J., Cully, J.A., Kunik, M.E. (2009). Cognitive behavior therapy for older adults with generalized anxiety disorder in primary care: A randomized clinical trial. Journal of the American Medical Association, April, 301(14):1460-1467. PMID: 19351943

Wetherell JL, Ayers CR, Sorrell JT, Thorp SR, Nuevo R, Belding W, Gray E, **Stanley MA**, Areán PA, Donohue M, Unützer J, Ramsdell J, Xu R, Patterson JL. (2009). Modular psychotherapy for anxiety in older primary care patients. American Journal of Geriatric Psychiatry, June, 17(6):483-492. PMID: 19461257

Kunik ME, Veazey C, Cully JA, Souchek J, Graham DP, Hopko D., Carter R., Sharafkhanek A, Goepfert EJ, Wray N, **Stanley MA.** (2008). Randomized controlled trial of education and cognitive behavioral therapy for depression and anxiety in COPD patients. Psychological Medicine, 38:385-396. PMID: 17922939

Stanley MA, Hopko DR, Diefenbach GJ, Bourland SL, Rodriguez H, Wagener P. (2003). Cognitive behavior therapy for late-life generalized anxiety disorder in primary care (CBT-GAD/PC): Preliminary findings. The American Journal of Geriatric Psychiatry, 11, 92-96. PMID: 12527544

Stanley MA, Beck JG, Novy DM, Averill PM, Swann AC, Diefenbach GJ, Hopko DR. (2003). Cognitive behavioral treatment of late-life generalized anxiety disorder. Journal of Consulting and Clinical Psychology, 71, 309-319. PMID: 12699025

Additional recent publications of importance to the field (in chronological order)

Veazey, C., Cook, K.F., **Stanley, M.A.,** Lai, E., & Kunik, M.E. (2009). Telephone administered cognitive behavorial therapy: A case study of anxiety and depression in Parkinson's Disease. Journal of Clinical Psychology in Medical Settings, September, 16(3), 243-253.

Paukert AL, Phillips L, Cully JA, Loboprabhu SM, Lomax JW, **Stanley MA.** (2009). Integration of religion into cognitive behavioral therapy for geriatric anxiety and depression. Journal of Psychiatric Practice, March, 15(2):103-112. PMID: 19339844

Kraus CA, Seignourel P, Balasubramanyam V, Snow AL, Wilson NL, Kunik ME, Schultz PE, **Stanley MA.** (2008). Cognitive behavioral treatment for anxiety in patients with dementia: Two case studies. Journal of Psychiatric Practice, May, 14:186-192. PMID: 18520790

Stanley MA, Veazey C, Hopko D, Diefenbach G, Kunik M. (2005). Anxiety and depression in chronic obstructive pulmonary disease: A new intervention and case report. Cognitive and Behavioral Practice,

12, 424-436.

C. Research Support
Current Support

R01-MH53932 (2nd renewal) **Stanley, M.A. (PI)** 2008-2013
National Institute of Mental Health
CBT for late-life GAD in primary care: Enhancing outcomes and translational value
The goal of this project is to test a model of care for late-life anxiety designed to enhance translational value and improve outcomes. Effects of the intervention delivered by experts and non-experts will be compared.
Role: PI

R34-MH078925 **Stanley, M.A. (PI)** 2007-2010
National Institute of Mental Health
Cognitive behavior therapy for anxiety in dementia
The goal of this project is to develop and pilot test a treatment for anxiety in patients with dementia.
Role: PI

1 R01 MH085527-01A1 Giordano (PI) 09/29/09 – 07/31/14
National Institutes of Health, NIMH
Test of an intervention to improve retention in HIV care after hospitalization
The goal of this project is to conduct a randomized, controlled, trial of a patient-mentor based intervention to improve retention in HIV care among patients hospitalized with HIV infection.

Completed Projects
Grant **Stanley, M.A. (PI)** 2008-2009
Pilot Study Research Program, South Central Mental Illness Research, Education, and Clinical Center (MIRECC)
Incorporating religion and spirituality into CBT for depressed and anxious older adults
Role: PI

R01-MH53932 (renewal) **Stanley, M.A. (PI)** 2003-2008
National Institute of Mental Health
Treatment of late-life GAD in primary care
The goal of this project is to examine the utility of cognitive behavior therapy, relative to usual care, for generalized anxiety disorder among older primary care patients. The PI is responsible for general administrative oversight and clinical supervision of treatment providers for this project.
Role: PI

Project IIR 00-097 Kunik, M.E. (PI) 2002-2005
Health Services Research and Development (HSR&D)
A cognitive behavioral intervention for depression and anxiety in COPD
The goal of this project was to examine the efficacy of an intervention targeting both anxiety and depressive symptoms in patients with chronic obstructive pulmonary disease. Dr. Stanley's primary role in this project involved development of the treatment manual and clinical supervision of project evaluators and therapists.
Role: Co-Investigator

R01-MH53932 **Stanley, M.A. (PI)** 1996-2003
National Institute of Mental Health
Treatment of generalized anxiety disorder in the elderly
The major goal of this project was to examine the post-treatment and long-term efficacy of cognitive-behavior therapy for generalized anxiety disorder in older adults.
Role: PI

Protocol Synopsis

Behavioral Treatment of Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study

Protocol Number	Clinical Research Mentored Grant
Protocol Title	Behavioral Treatment of Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study
Clinical Phase	Phase II
Investigators	Parkinson Study Group (PSG)
Study Centers	2
Study Period	One year
Study Objective	The proposed study will pilot an evidence-based cognitive-behavioral therapy (CBT) intervention for anxiety for individuals with Parkinson's disease (PD). This study will provide the preliminary data necessary for designing a future randomized clinical trial (RCT), including information on the feasibility and acceptability of a CBT intervention for patients with anxiety and PD.
Study Population	Individuals with idiopathic Parkinson's disease and significant anxiety
Study Design	Participants will be recruited from the Parkinson's Disease Center and Movement Disorder Clinic (PDCMDC) at Baylor College of Medicine and the Parkinson's Disease Research and Education Center (PADRECC) at the Michael E. DeBakey VA Medical Center by provider and self-referrals. Only patients who complete the informed consents and screen positive on the HADS will be asked to complete the remainder of screening assessments (MOCA and diagnostic interview SCID-I/P).After we have determined inclusion status and patients have completed a baseline assessment, we will randomly assign them to receive either the CBT treatment or enhanced usual care. They will complete the measures again at 3 months (post-treatment), and 4 months (1-month follow-up). CBT consists of 8-weekly sessions, each approximately 45 minutes. Patients assigned to enhanced usual care will continue on current treatment regimens provided to them by their healthcare providers. Anxiety and co-occurring depressive symptoms will be monitored monthly by telephone assessments.
Number of Subjects	20
Main Inclusion Criteria	Patients will be included if they (1) have a confirmed diagnosis of idiopathic PD based on UK Brain Bank criteria by a movement disorder specialist, and (2) have

	significant anxiety, as indicated by a score ≥ 6 on the Hospital Anxiety and Depression Scale (HADS) anxiety subscale.
Main Exclusion Criteria	Patients will be excluded if they have significant cognitive dysfunction or possible dementia, as defined by the Montreal Cognitive Assessment (MoCA < 23), or if they have conditions that threaten their immediate safety, including active suicidal intent; current uncontrolled, disruptive psychosis; bipolar and/or substance-abuse disorders; or impulse-control disorders within the past month
Route and Dosage Form	Cognitive Behavior Therapy
Dosage	45-minutes weekly sessions
Duration of Treatment	8 sessions over the course of 12 weeks
Primary Outcome Measure	Anxiety: Hamilton Anxiety Rating Scale
Secondary Outcome Measures	Quality of life (Parkinson's disease questionnaire-8); depression (Geriatric Depression Scale -15 and Hamilton Depression Scale); Satisfaction with treatment (Client Satisfaction Questionnaire; Exit Interview) and caregiver measures of burden (Caregiver Burden Inventory) and depression (Patient Health Questionnaire -9)
Sample Size Considerations	Sample size of 20 for a small controlled pilot to estimate effect sizes and assess feasibility and acceptability.

Schedule of Activities

Behavioral Treatment of Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study.

	Screening	Baseline (IE)	Treatment Phase (Months 1-3) 8 Sessions of CBT or Enhanced Usual Care	3-Month (IE)	1-Month Follow-up (IE)
Written Informed Consent	X				
Patient Assessments					
Hospital Anxiety and Depression Scale	X	X		X	X
Montreal Cognitive Assessment	X				
Structured Diagnostic Interview for DSM-IV	X				
Hamilton Anxiety Rating Scale		X		X	X
Geriatric Depression Scale-15		X		X	X
Hamilton Depression Rating Scale		X		X	X
Parkinson's disease questionnaire-8		X		X	X
Patient and Caregiver Assessments					
Client Satisfaction Questionnaire				X	
Exit Interview				X	
Caregiver Only Assessments					
Caregiver Burden inventory		X		X	X
Patient Health Questionnaire-9		X		X	X

Career Development Plan

Candidate's Background

I am currently an assistant professor in the Menninger Department of Psychiatry at Baylor College of Medicine (BCM), Houston, Texas, and a clinical research psychologist at the Michael E. Debakey Veterans Affairs Medical Center. I joined the faculty at BCM in June 2010 with an interest in pursuing clinical experience and research funding to provide treatment for anxiety and depression in patients with PD. However, my interest and expertise in this specific area evolved through the course of my education and training. During my graduate and post-graduate training in clinical psychology, I developed specialized skills in cognitive-behavior therapy (CBT), treatment for anxiety, and providing mental health care to older medical patients. My interests have been in the implementation of CBT treatment in non-traditional (health care or home) environments to increase access to evidence-based care. After completing an internship at BCM, with a focus on CBT for anxiety disorders, I worked as a fellow on the CBT for Late-Life GAD: Enhancing outcomes and translational value (R01-MH53932), providing CBT to older adults with GAD and assisting in project administration, supervision of research assistants, manuscript preparation, and presentations at national conferences. During my fellowship, I also had the opportunity to develop expertise in CBT for anxiety in patients with dementia, while working with Dr. Stanley on another NIMH-funded study (R34-MH078925).

Currently, I receive funding through a supplement to an ongoing R01 (Stanley: MH53932) to study the mediating role of executive functioning in CBT for late-life GAD in primary care. This funding also provides support for clinical and research development, which includes training in neuropsychology and everyday functioning for older adults with neurological impairments. As part of the training, I have conducted neuropsychology assessments, observed neurology exams, and participated in psychiatric assessments in the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) Parkinson's Disease Research and Education Clinical Center (PADRECC). From my experiences in the PADRECC, my interest and excitement in providing accessible evidence-based mental health care for patients with Parkinson's disease (PD) began. Recently, I received 1-year pilot funding for treatment development for a CBT protocol for anxiety and depression in PD from the South Central Mental Illness Research, Education and Clinical Center. The PSG mentored award training program and pilot study, combined with the recent treatment development grant, would provide me with the opportunity to develop a framework for larger research studies examining treatments for anxiety in patients with PD.

Career Goals and Objectives

My goals in the next year are to develop, refine and pilot a treatment for anxiety provided in collaboration with PD clinics. My long-term goals are to pursue a career as an independent researcher in the implementation of tailored mental health treatments for patients that improve decrease anxiety and improve quality of life. With the guidance and expertise of Drs. Stanley and Marsh, this proposed study and training plan will help to establish the need, build investigator expertise in this area and set the groundwork, as well as provide preliminary data for future grant applications proposing large, multisite trials for CBT for anxiety in PD. My background in clinical psychology and experience in working in intervention studies with older adults with and

without dementia provide unique skills for treating patients with PD. The training plan will help to extend my clinical experience and knowledge of clinical care of patients with PD, clinical trials, and grant writing.

The specific career development goals are to:
1. Develop knowledge regarding clinical assessment and care of PD:
    - Study the phenomenology of motor, cognitive, and psychiatric symptoms of PD.
    - Evaluate the potential role of motor and cognitive symptoms in outcomes following treatment.
2. Improve skills in clinical design and methodology.
    - Increase understanding of research design and analyses, with particular focus on understanding the methods of design implementation in healthcare settings and treatment outcome studies.
    - Improve understanding of measurement involved in assessing change over time.
3. Develop advanced skills in manuscript and grant writing.
    - Publish at least 3 to 4 scientific manuscripts in peer-reviewed journals per year.
    - Prepare future grants: National Parkinson's Foundation grant award and DVA Career Development Award or NIH K-award.

Career Development Activities

The training goals will help achieve my short- and long-term goals of gaining clinical knowledge and expertise in research design methods and scientific writing. To meet the training goals, activities will include direct clinical training and didactics. The didactics consist of seminars, workshops, and conferences. Training also includes ongoing research participation from the proposed project and supervision by and consultation with mentors.

Clinical assessment and care of PD: Direct clinical training

Provision of mental health care at PADRECC: Under the supervision of Dr. Marsh, I will provide mental health care to outpatients with PD at the PADRECC during ½ day a week. The patients will include new patients for evaluation, as appropriate, and individuals needing individual psychotherapy outside a research study.

Observation at the Parkinson's Disease and Movement Disorders Clinic (PDMDC): To enhance my understanding of PD, I will spend a ½ day per week for 6 months at the PDMDC. The structured observation of neurology exams and direct care by neurologists will provide real-world instruction on the clinical phenomenology and health care for PD and related movement disorders.

Clinical assessment and care of PD: Didactic training

A weekly video case conference is presented at the PDCMDC to broaden knowledge about phenomenology and treatment of PD and movement disorders.

The PADRECC weekly journal club is attended by neurologists, neuropsychologists and others healthcare providers and researchers interested in movement disorders.

The neurobehavioral seminar series and case conferences at BCM offer didactics highlighting the interplay between emotional and cognitive functioning and occur monthly.

I will attend the 21st Annual Summer Movement Disorders course: A Comprehensive review of movement disorders for the clinical practitioner. The course is designed for varied levels of health professionals from the beginner to the experienced to increase their knowledge of movement disorders. The summer course is offered over 4 days in July 25 - 28, 2011.

Clinical design, methodology, and professional writing: Supervision, consultation, meetings
Dr. Marsh and I will meet bi-weekly to discuss progress and developments in the proposed project and grant preparations for future projects. Dr. Marsh is a member of the Parkinson's Study Group, a professor in the Department of Psychiatry and Behavioral Sciences and the Department of Neurology and the Mental Health Care Line executive at the MEDVAMC. Dr. Marsh's research and clinical efforts focus on improving the recognition and treatment of neuropsychiatric aspects of PD. Dr. Marsh will work closely with me to provide supervision of outpatient assessments and care and career development activities.

Dr. Calleo will meet weekly with her co-mentor, Dr. Stanley, for 1 hour of individual mentorship and 1 hour of project meetings. Dr. Stanley is professor and head of the Psychology Division in the Menninger Department of Psychiatry and Behavioral Sciences at BCM. She has a long history of research funding, with a particular focus on developing and testing cognitive-behavioral interventions for older adults with anxiety. She also has significant experience in mentorship of postdoctoral fellows and junior investigators. Supervision will include mentorship on research methods of clinical trials, manuscript collaborations, and other grant-preparation activities.

Attend weekly meetings of the CBT for Late-Life GAD: Enhancing outcomes and translational value R01, at which time Dr. Stanley and co-investigators, clinicians, and staff meet to determine the diagnostic consensus for patients in the study, in addition to discussing the direction and progress of future trials.

Clinical design, methodology, and professional writing: Didactic training
Professional development seminars are offered at the Houston VA Health Services Research & Development Center of Excellence. I will attend weekly seminars designed for junior investigators that include topics on grant and scientific writing, health services research, and health research methods. I will also participate in a weekly research-in-progress seminar, in which researchers pose questions regarding study design, methods, analysis, result interpretation, dissemination, and grantsmanship.

I am attending a statistics workshop at the University of Texas Summer Statistics workshop on Hierarchical Linear Modeling for social scientists. The course includes statistics such as growth-curve analysis that will help me analyze outcome effects. Dr. Bush will also be available for consultation for statistics needed to analyze outcomes on this project and design of future project.

Clinical design, methodology, and professional writing: Conferences
I will attend and present findings at the annual Parkinson's Study Group conference.

I will attend and present findings at the national conference for the American Association of Geriatric Psychiatry and/or Gerontological Society of America.

Training in the responsible conduction of research

I have completed the Collaborative Institutional Training Initiative (CITI) training for in ethical conduct in human subject research, including modules on ethical principles, informed consent, research with vulnerable populations, research misconduct, and ethics in social and behavioral research**.**

DEPARTMENT OF VETERANS AFFAIRS
Michael E. DeBakey VA Medical Center
2002 Holcombe Boulevard
Houston, TX 77030

In Reply Refer To: 580/116

Mental Health Care Line (116)
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2002 Holcombe Boulevard
Houston, TX 77030
OFFICE 713-794-8907/FAX 713-794-7917
Email: laura.marsh2@va.gov

Laura Marsh, M.D.
Executive Director, Mental Health Care Line
Michael E. DeBakey Veterans Affairs Medical Center
Professor, Departments of Psychiatry and Neurology
Baylor College of Medicine

March 12, 2011

Parkinson Study Group Grant Adjudication Committee
Re: Application of **Dr. J. Calleo** for the PSG Mentored Clinical Research Award

Dear Committee Members,

This letter is in support of the application of **Jessica Calleo, Ph.D.** for the **Parkinson Study Group (PSG) Mentored Clinical Research Award entitled "Behavioral Treatment of Anxiety in Parkinson's Disease (BehTA-PD): A Pilot Study**". Dr. Calleo became an Assistant Professor at Baylor College of Medicine in June, 2010 and holds a joint appointment as a clinical research psychologist at the Michael E. DeBakey Veteran Affairs Medical Center (MEDVAMC). Her background is as a psychologist, with clinical expertise in providing cognitive-behavior therapy (CBT) for anxiety disorders and experience with mental health care in older adults. Her research has focused on the development and implementation of effective treatments and interventions for individuals with late-life anxiety disorders. Dr. Calleo is relatively new to the clinical area of Parkinson's disease (PD); she enjoys working with the patients and has found the clinical mood symptoms amenable to behavioral psychotherapeutic interventions. Importantly, she is now applying her clinical and research expertise to address an important clinical problem that is understudied in PD, and for which there is no evidence-based guidance on its management. Thus, the PSG Mentored Clinical Research Award would support the development of an early career researcher with a successful track record to date, but who is new to the area of PD and would bring to the PSG a new and important area of research focus for future clinical trials sponsored by the PSG.

Dr. Calleo is currently funded by a research supplement to an R01 (PI: Stanley, MH53932) and a clinical/research position supported at the MEDVAMC. She joined the Baylor faculty with the motivation to begin a career in providing accessible evidence-based care for anxiety in PD. Her current position provides protected research time but no funds to support additional educational experiences or clinical research projects. The PSG Mentored Award will provide Dr. Calleo the opportunity to learn more about clinical aspects of PD and the funds to carry out a pilot study on CBT of anxiety, which is necessary to provide preliminary data that will inform and support the development of larger multi-site trials for anxiety treatment in PD. The PSG funds will also provide support for biostatistical consultation and part-time personnel support of a graduate student research student. The research student will help Dr. Calleo manage the study and conduct the proposed treatment for the pilot study.

I am pleased to provide mentorship to Dr. Calleo during the award period. It has been a pleasure to work with her in the past year since she has been at the MEDVAMC. We worked together on submission of a treatment development pilot study for anxiety in PD. This project involves development and adaptation of CBT procedures for patients with PD and anxiety and is now being funded through the VA Mental Illness Research and Education Clinical Centers (MIRECC) grant program. We are also collaborating on the preparation of three manuscripts. Dr. Calleo works well independently as well as collaboratively, accepts feedback easily, and follows through on the execution of her projects in a timely manner. For this proposal, I will provide direct training and supervision in clinical care and clinical research on psychiatric assessments and treatment for anxiety in PD. We will meet bi-weekly to discuss Dr. Calleo's research project as well as her ongoing progress on manuscripts and future career developmental activities.

The opportunity to provide specialized training for a psychologist specializing in older adult care is exciting and much needed, especially given that long-term disability and morbidity in PD are related to its non-motor cognitive and psychiatric disturbances. However, psychologists involved in psychotherapeutic care and research are generally unfamiliar with the clinical aspects of movement disorders and, typically, do not get the opportunity to work collaboratively in PD specialty clinics. Enhanced training of psychologists would facilitate an effective multidisciplinary approach of patients with PD and promote research on its neuropsychiatric disturbances.

The resources and environment at Baylor College of Medicine and MEDVAMC are excellent for Dr. Calleo to conduct the proposed work, facilitate growth of her research to the next level, and gain further education on clinical aspects of PD. In addition to the well-established movement disorders program directed by Dr. Jankovic at Baylor College of Medicine, which saw over 3000 patients with PD last year, the MEDVAMC Parkinson's Disease Research and Education Clinical Center (PDRECC) follows about 600 patients with PD, actively engages in research, and became a new PSG site last year. Thus, subject accrual and exposure to PD patients with varied forms of anxiety disturbances should be straightforward. We also have an excellent established formal mentoring infrastructure for junior faculty within the Department of Psychiatry and MEDVAMC that already meets with Dr. Calleo. In addition to myself, Dr. Calleo's team includes her co-primary mentor, Melinda Stanley, Ph.D., an expert on late-life anxiety disorders and their treatment. Dr. Stanley has a long track record of federal funding and successful mentorship in this area. Mark Kunik, M.D., another member of Dr. Calleo's mentoring team, is a geriatric psychiatrist with expertise in health services research and funded research on management of behavioral disturbances in dementia.

My own research qualifications include extensive work in the area of neuropsychiatric aspects of Parkinson's disease. This includes descriptive clinical studies, investigator-initiated and industry-sponsored clinical trials, and neuroimaging investigations. From 1998-2009, I directed the Clinical Research Core of the Morris K. Udall Parkinson's Disease Research Center of Excellence at Johns Hopkins as well as my own funded research program. I am also a member of the Advisory Boards for the National Parkinson Foundation and the American Parkinson's Disease Association, a member of the PSG Scientific Review Committee, and a co-chair of the PSG Cognitive/Psychiatric Work Group. I continue to mentor and work collaboratively with junior investigators, including Greg Pontone, MD, a previous PSG Mentored Career Awardee. In 2009, I moved to Houston, TX to assume the position as director of the MEDVAMC Mental Health Care Line and join the faculty in the Departments of Psychiatry and Neurology at Baylor. A major focus of my current work in PD involves identifying and implementing strategies that improve recognition and treatment of psychiatric disturbances and better integrate mental health care and related services into non-mental health settings.

I believe that Dr. Calleo is an excellent candidate for PSG support through its Mentored Clinical

Research Award. She has considerable experience in cognitive behavior therapy for anxiety and as a member of a clinical research team; she now needs additional time to improve her knowledge and skills in the areas of PD-specific mental health care and to learn more about the design, methods and analysis of clinical trials, research funding, and the implications of her findings. The present funding provides an opportunity for Dr. Calleo to gain this experience and the preliminary data necessary to develop as an investigator and clinician in a supportive and high-quality clinical and research environment.

Thank you in advance for consideration of her application.

Yours sincerely,

Laura Marsh, MD

BCM
Baylor College of Medicine

Melinda A. Stanley, Ph.D.
Professor
Head, Division of Psychology
The McIngvale Family Chair
in Obsessive Compulsive
Disorder Research
Menninger Department of Psychiatry
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March 9, 2011

Parkinson Study Group Grant Adjudication Committee
Parkinson Study Group Mentored Clinical Research Award

Re: Dr. Jessica Calleo

Dear Committee Members,

I am very pleased to write this letter in support of Dr. Jessica Calleo who is applying for a Parkinson Study Group (PSG) Mentored Clinical Research Award. I have known Dr. Calleo since 2005 when she began work as a study clinician in our late-life anxiety research program. As a graduate assistant, she also served as a project coordinator for one of our studies and utilized data from one of our clinical trials for her dissertation. Dr. Calleo completed her predoctoral psychology internship in our Department and then worked with us for two years as a post-doctoral fellow. During that time, she prepared an application for a diversity supplement to our ongoing NIMH R01 (MH53932) that would support her continued professional development and a research project to examine the impact of executive dysfunction on outcomes following cognitive behavior therapy (CBT) for late-life generalized anxiety disorder (GAD). She received this award in June 2010 and at the same time was appointed Assistant Professor of Psychiatry and Behavioral Sciences. As part of Dr. Calleo's diversity supplement, she is developing specialized expertise in the treatment of anxiety among patients with Parkinson's Disease (PD). She is well poised to become a national expert in this area given her strong background in CBT for anxiety and the unique combination of mentorship available to her in psychosocial clinical trials (Stanley) and neuropsychiatry of PD (Marsh). This is an important area of study given that anxiety is prevalent among patients with PD, but no evidence-based guidelines exist for treatment. Although Dr. Calleo's diversity supplement covers 75% of her salary, this award carries no substantial support for other research expenses. Thus, the PSG Mentored Clinical Research Award would provide much needed support for a part-time research assistant, biostatistics support, supplies, and patient payments.

I have known Dr. Calleo for a long time, and I think very highly of her. It has been a pleasure to watch her move toward a career as an independent researcher. Dr. Calleo originally came to our group with interests in a clinical and teaching career, but over the past 6 years her career goals have made a rather dramatic turn toward establishing herself as an independent researcher with expertise in CBT for anxiety in older adults. Dr. Calleo has excellent training in CBT theory and techniques, and she served effectively as a clinical supervisor in this domain while working with us. Her skills in manuscript writing and grant preparation also are developing well, and she has established a nice early career curriculum vitae. Dr. Calleo is learning how to conceptualize and lead research projects, and I like the projects she is developing. As she has grown increasingly committed to developing a career in clinical research, she has actively sought out additional experiences to inform her career development. Of particular note, she applied for and was selected to attend an NIMH-sponsored Summer Research Institute in 2009 where she made contacts with national scientists and received feedback about the project she had proposed for the supplement application. This experience led to the development of a relationship with Dr. George Alexopoulous, a national expert in the role of executive dysfunction in the treatment of late-life depression, and with a number of senior NIMH administrative staff who have provided ongoing input into Dr. Calleo's career directions.

I am fully committed to continuing to provide Dr. Calleo with research mentorship during the award period (and beyond) to help her achieve her goal of becoming an independently funded investigator with expertise in anxiety treatment among older adults with PD and other chronic medical problems. The mentorship I provide will involve oversight in the design and methodology of psychosocial clinical trials, professional development in the field of psychology and clinical research, grant writing, and preparation of scientific manuscripts. Dr. Calleo and I

currently meet at least twice weekly in the context of research team meetings and individually scheduled mentor meetings. We will continue this schedule throughout the duration of the proposed training award. Dr. Calleo and I also have offices in the same Health Services Research and Development Center, which facilitates informal meetings as needed, and we communicate regularly via telephone and electronic mail.

I am well qualified to serve as Dr. Calleo's mentor given my history of research funding that focuses on the development and testing of cognitive behavioral interventions for older adults with anxiety. I also have significant experience in the mentorship of junior faculty. I have served as a mentor or consultant on three K23 grants, two Veterans Affairs Career Development Awards, and two NIH Diversity Supplements. I have a strong publication record, have served as a reviewer for NIMH, and am a Fellow of the American Psychological Association, Division 12 (Clinical Psychology).

I believe that Dr. Calleo is an outstanding candidate for a PSG Mentored Clinical Research Award. In addition to her research and clinical competence, Dr. Calleo has a calm and engaging interpersonal style that has helped her to develop strong interdisciplinary relationships with other members of the research team and with our clinical partners. She is also well organized and thorough in her work, and she is a real pleasure to have as a junior collaborator. I look forward to continuing to work with and mentor Dr. Calleo over the course of the PSG award.

Sincerely,

Melinda Stanley

Melinda A. Stanley, Ph.D.

Houston Center for Quality of Care & Utilization Studies
HCOCUS

Laura A. Petersen, MD, MPH
Director
Chair, Leadership Team
Associate Director; Chief,
Health Policy and Quality Division

Hashem B. El-Serag, MD, MPH
Associate Director; Chief,
Clinical Epidemiology and Outcomes
Division

Mark E. Kunik, MD, MPH
Associate Director; Chief,
Health Services Delivery and
Organization Division

Richard L. Street, PhD
Associate Director; Chief,
Health Decision-Making and
Communication Division

Cynthia Nelson, MS
Acting Chief, Operations Division

March 10, 2011

Jessica Calleo, Ph.D.
Houston VA HSR&D Center of Excellence
Baylor College of Medicine

Dear Dr. Calleo:

I am very pleased to serve as expert consultant in your application for a Parkinson's Study Group Mentored Research Award. As a geriatric psychiatrist and researcher with significant expertise in the treatment of dementia, collaborative care models, and mental health services research, I am aware of the importance of increasing access to mental health treatment for older adults. I have enjoyed our collaboration on previous projects in the context of Dr. Stanley's primary care study and supplement (MH5393).

I shall be happy to assist you in reaching your research and career development goals. We have been meeting twice a month for reading tutorials and career guidance, and I am committed to continue this effort at this level. I look forward to continued collaborations.

Yours sincerely,

Mark E. Kunik, MD, MPH
Professor of Psychiatry and Behavioral Sciences, Baylor College of Medicine
Associate Director, Houston Center for Quality of Care & Utilization Studies
Geropsychiatry Health Service Research, Houston VAMC

Michele K. York, Ph.D.
Section Head, Neuropsychology
Assistant Professor
Department of Neurology

March 16, 2011

Jessica Calleo, Ph.D.
Houston VA HSR&D Center of Excellence
Baylor College of Medicine

Dear Dr. Calleo:

I am very pleased to serve as an expert consultant for your application to the Parkinson's Study Group Mentored Clinical Research Award. As a neuropsychologist with expertise in the cognitive correlates of Parkinson's disease, I find your proposal examining cognitive behavior therapy for anxiety in Parkinson's disease an exciting and important project. I have enjoyed providing supervision and training to you regarding neuropsychological assessments in Parkinson's disease and welcome the opportunity to participate on this project and career development plan.

I am happy to assist you in any way that I can as you begin to implement your research and career development and to support the project. During the time of the mentored research award, I will provide feedback and consultation on the pilot study utilizing my experience with working with patients with Parkinson's disease. I look forward to continuing our collaboration on this and future projects.

Sincerely,

Michele K York

Michele York, Ph.D.
Assistant Professor of Neurology and Psychiatry
Section Head, Neuropsychology

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JOSEPH JANKOVIC, MD
Professor of Neurology,
Department of Neurology
Distinguished Chair in Movement Disorders,
Director, Parkinson Disease Center and
Movement Disorders Clinic,
Director, National Parkinson Foundation Center
of Excellence,
Director, Huntington's Disease Society of America
Center of Excellence

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March 11, 2011

Jessica Calleo, Ph.D.
Assistant Professor
Menninger Department of Psychiatry and Behavioral Sciences
Baylor College of Medicine
Michael E. DeBakey Veteran Affairs Medical Center
2002 Holcombe Boulevard
Houston, Texas 77030

Dear Dr. Calleo,

I am pleased to write in support of your application for the Mentored Clinical Research Award from the Parkinson's Study Group (PSG) for your project entitled, **"Behavioral Treatment of Anxiety in Parkinson's Disease (BEhTa-PD): A Pilot Study."** Anxiety is a significant and disabling problem for many patients with Parkinson's disease (PD) and it frequently complicates our management of their motor symptoms. Your study addresses an important clinical area where there has been little research to date, and, in particular, no studies on the treatment of anxiety. I appreciate your efforts to integrate evidence-based psychotherapeutic treatments for anxiety into the care of patients with PD. Thus, your proposal to the PSG is not only novel, but most appropriate as a PSG application as it will set the stage for larger scale multi-site clinical trials on behavioral treatments.

I look forward to collaborating with you on the execution of your proposal through our clinic at the Parkinson's Disease and Movement Disorders Center (PDMDC) at Baylor College of Medicine. Our site has been involved with the PSG since its inception. We treat over 3,000 patients with PD annually, and have an active research program with established procedures for successful recruitment into studies. In addition to supporting the research component of your proposal, I look forward to having you continue to take part in our center's educational programs, so as to advance your knowledge of movement disorders.

It is exciting to be a part of your effort to expand our approaches to the treatment of non-motor aspects of PD in ways that have great potential to enhance the lives of our patients.

With kind regards,

Joseph Jankovic, MD

CHECKLIST
Attachment 3

Type of Application:

X NEW application

□ RESUBMISSION of application submitted (date previously submitted)_____

Does your submission include the following?

X Cover letter

X Face Page (Attachment 1)

X Narrative not extending 5 pages (not including references) and including: specific aims of the study, background, preliminary studies, research design and methods, plus references, and a protocol synopsis and schedule of activities, if applicable (Attachment 2);

X Budget

X Budget justification

X Biosketches for PI and co-PIs on project

Please answer the following questions:

1. Do you assure unrestricted access to the study database (if applicable)? N/A

2. Do you assure unrestricted right to publish all results? Yes

3. Is a study steering committee in place, with appropriate expertise? If not, is there an adequate plan for identifying a steering committee? (if applicable) N/A

4. Is there appropriate provision for study coordination? Yes.

5. Is there appropriate data management and biostatistical support? Yes.

6. Are there human subjects concerns in your proposal? Yes.

7. Does your proposal pose any conflict-of-interest or potential conflict-of-interest? No.

8. Will you agree to provide to the PSG any new data obtained and a copy of your analysis? Yes.

THIS SHOULD BE YOUR LAST PAGE, NUMBERED