Date: Monday, April 4, 2022 2:55:37 PM Print Close

HP-00072447 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
PEER for Older Veterans

2 * Full Title:
Peer Support for Exercise for Older Veterans with Mental Illness

3 Official title: Peer Support for Exercise for Older Veterans with Psychotic Disorders NCT02958007

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

HP-00072447

Research Team Information_V2

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Anjana Muralidharan

CITI Training:

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Sera Havrilla

CITI Training:

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Lorrianne Kuykendall	no	no	Research Team Member	no	
View	Melanie Fischer	no	no	Research Team Member	no	
View	Cynthia Giron-Hernandez	no	no	Research Team Member	no	
View	Jeffrey Beans	no	no	Research Team Member	no	ID00006931
View	Steven Yoo	no	no	Research Team Member	no	
View	Brian Phipps	no	no	Research Team Member	no	
View	Leslie Katzel	no	no	Sub-Investigator	no	ID00008791
View	Richard Goldberg	no	no	Sub-Investigator	no	ID00008960
View	Gabriella Coakley	no	no	Research Team Member	no	
View	Belinda Kauffman	no	no	Research Team Member	no	ID00009489
View	Laura Mastella	no	no	Research Team Member	no	ID00006591
View	Jamie Giffuni	no	no	Research Team Member	no	
View	Lijuan Fang	no	no	Statistician	no	
View	Amanda Peeples	no	no	Research Team Member	no	
View	Steven Prior	yes	no	Sub-Investigator	no	ID00008139
View	Kinnera Atluri	no	no	Research Team Member	no	
View	Kelly Lloyd	yes	yes	Research Team Member	no	
View	Lynda Robey	yes	yes	Research Team Member	no	ID00005538
View	Clayton Brown	no	no	Statistician	no	ID00000679
View	Howard Turner	no	no	Research Team Member	no	
View	Kirsten Harvey	no	no	Research Team Member	no	
View	Tracy Robertson	no	no	Research Team Member	no	
View	Alicia Lucksted	no	no	Sub-Investigator	no	ID00001635
View	Jeanette Robinson	no	no	Research Team Member	no	ID00008752
View	LAN LI	no	no	Statistician	no	

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

HP-00072447 Resources_V2

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
Dr. Muralidharan will devote a portion of her time to conduct and complete this research study.

2 * Describe the facilities where research procedures are conducted:
The project will be completed at the VAMHCS.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
We do not anticipate that participants will need medical or psychological resources following their participation in this minimal risk study. However, the VA does provide medical and/or psychological treatment for participants who take part in VA research, as outlined in the mandated VA consent form.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Study staff working on this protocol will be specifically trained to perform their assigned duties on this project, which will be described to them in detail. They will become very familiar with the protocol through ongoing study team meetings. MIRECC research staff are extensively trained on working with participants with serious mental illness and obtaining informed consent. Study staff practice study procedures beforehand and are observed a number of times prior to meeting with a research participant alone. Furthermore, they are observed on a quarterly basis obtaining informed consent. Supervision for those conducting the manualized treatment intervention will be held on a regular basis by Drs. Muralidharan and Goldberg.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ● **No**

6 * Institution(s) where the research activities will be performed:

- ☐ University of Maryland, Baltimore
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☑ **VAMHCS**
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)

- [ ] National Study Center for Trauma and EMS
- [ ] Univ of MD Cardiology Physicians at Westminster
- [ ] Nursing Homes in Maryland
- [ ] University of Maryland Biotechnology Institute
- [ ] Maryland Department of Health
- [ ] Maryland Proton Treatment Center
- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [ ] University of Maryland Medical System (Select below)

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:

- [x] **Federal**
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [x] **Participant Compensation**
- [ ] Procedures
- [ ] Other

3 Please discuss any additional information regarding funding below:

ID: VIEW4DF85DF452400
Name: v2_Funding Information

HP-00072447 DHHS Funded Study_V2

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

◯ Yes ● **No**

2 You may upload any grant documents here:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1 * Agency Name:
VA Rehabilitation Research and Development Service (RR&D)

* Address 1:
810 Vermont Avenue NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20420

* Contact Person:
Shirley Groer

* Phone Number:
202-443-5767

* Federal Agency Email:

Grant Number 1 (if applicable):
1 IK2 RX002339-01A1- OR - Check here if Grant 1 is not assigned a number. ☐

If Grant 1 has no number, please provide the following information:
Title of Grant 1:

PI of Grant 1:

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☑

If Grant 2 has no number, please provide the following information:
Title of Grant 2:
University of Maryland Claude D. Pepper Older Americans Independence Center Pilot
PI of Grant 2:
Anjana Muralidharan

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

ID: VIEW4DF8584874400
Name: v2_Federal Agency Sponsor Information

HP-00072447 Research Protocol_V2

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

HP-00072447

Risk Level_V2

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [ ] Use of device(s) whose use is specified in the protocol
- [x] **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- [x] **Sample (Specimen) Collection and/or Analysis (including genetic analysis).**
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

(●) **Yes** ( ) No

ID: VIEW4E0280569E000
Name: v2_Type of Research

HP-00072447

Lay Summary_V2

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Older adults with psychotic disorders experience a dual set of challenges: those related to serious mental illness, and those related to aging. They have medical, cognitive, psychological and social difficulties; as a result they have an almost four times greater likelihood of early institutionalization in nursing homes. These challenges make it difficult for this group to engage in health behaviors, such as exercise. This is unfortunate, since participation in health-promoting activities is essential for maintaining functional independence with age. This study aims to develop and pilot test a peer coaching intervention for older Veterans with psychotic disorders, in which VA Peer Specialists, who are Veterans in recovery from mental illness, will provide intensive coaching to older Veterans with psychotic disorders to promote their participation in exercise and physical activity. Results from this study will inform us as to whether this intervention is acceptable to Veterans, feasible to implement, and effective in increasing exercise, physical activity, and physical fitness/function.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Aim 1: Develop Peer Education on Exercise for Recovery (PEER), a group-based peer coaching intervention delivered by a VA Peer Specialist, to promote participation in supervised fitness training and daily physical activity. PEER will include a 12 week intensive coaching phase and a 12 week maintenance phase with stepped-down support.

Aim 2: Establish acceptability and perceived utility of PEER in an open trial with older Veterans with psychotic disorders (ages 50 and up, n=6).

Aim 3: Examine feasibility and preliminary efficacy of PEER in a pilot randomized controlled trial (RCT) with older Veterans with psychotic disorders (ages 50 and up, n=20).

Aim 4: Assess symptoms and functioning in an additional sample of older Veterans with psychotic disorders (n=18). The purpose of this aim is to increase the baseline sample size in order to have a more larger well-characterized sample, with which we can engage in hypothesis generating inquiry regarding the relationships among various mobility, symptom, and functioning measures.

Across Aims 2, 3, and 4, following initial chart screening, we estimate that we will enroll 60 participants. With these 60 participants, additional screening procedures will be conducted, and some participants will no longer be eligible. Then we will have final sample sizes of 6 for Aim 2, 20 for Aim 3, and 18 for Aim 4.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

Aim 1 design: To develop the intervention, materials from existing peer-delivered health and wellness interventions for Veterans with serious mental illness (SMI) will be tailored to the unique needs of older Veterans with psychosis through an iterative process of developing materials and obtaining feedback on drafts from two panels of experts. One panel will be Veterans who routinely advise MIRECC investigators on studies, and the other panel will be largely made up of expert researchers.

Aim 2 design: To establish acceptability, we will conduct an open trial with older Veterans with psychotic disorders (ages 50 and up; n=6). Acceptability and perceived utility will be demonstrated via qualitative Veteran interviews. Results will be used to further refine the intervention.

Aim 3 design: To examine feasibility and preliminary efficacy of PEER, we will conduct a pilot RCT. All participants will be enrolled in supervised fitness training. Participants will be randomized to receive group-based peer coaching (the PEER condition) or individual support from non-peer staff (the enhanced supervised fitness training condition, ESFT).

Feasibility will be demonstrated by adequate rates of recruitment, PEER intervention engagement, and peer coach fidelity to the intervention. We hypothesize that compared to ESFT, participants in PEER will exhibit greater (a) attendance of supervised fitness training, (b) increases in general physical activity, and (c) improvement in physical fitness and function over the intensive coaching phase.
We also hypothesize that group differences will remain significant at the end of the maintenance phase.

Aim 4 design: To assess symptoms and functioning in an additional sample of older Veterans with psychotic disorders, participants will complete the same battery of assessments as individuals in Aim 3 without participation in any intervention.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Structured exercise programs are highly effective in improving physical, cognitive, psychological, and social functioning in older adults. Exercise interventions also significantly benefit adults with psychotic disorders. However, older adults with psychosis exhibit low levels of physical activity and unique barriers to exercise participation, including prototypical features of psychosis (e.g., negative symptoms, medication side effects) and exacerbating features of the aging process (e.g., increased medical comorbidity, declines in musculoskeletal health). Pilot analyses I conducted provide some of the first evidence that older Veterans with psychotic disorders (n=9044) experience significantly more medical and psychosocial barriers to physical activity than their same-age peers or their younger counterparts. Strategies to empower these individuals to overcome barriers and participate in health-promoting activities, such as exercise, are sorely needed.

Peer support interventions, or interventions delivered by individuals who are similar to a patient population on some characteristic such as age or diagnosis, effectively promote engagement in health behaviors such as exercise. Peer-delivered exercise interventions for older adults promote exercise self-efficacy, initiation and maintenance of exercise behaviors, and increased levels of general physical activity. In addition, peer support interventions delivered by individuals with a lived experience of mental illness are an effective and integral component of recovery-oriented mental health care, and close to 900 Peer Specialists (Veterans in recovery from a mental illness) have been hired nationally as part of VA's recovery transformation. Despite the promise of peer support and urgent needs of older adults with psychosis, there are no well-specified peer support interventions that promote participation in health behaviors and are tailored to the needs of this group.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Over the next two decades, Veterans with psychotic disorders (i.e., schizophrenia spectrum disorders and affective psychoses) will age into older adulthood in unprecedented numbers. The aging process has a particularly detrimental impact on this population; older adults with psychotic disorders exhibit markedly diminished physical, cognitive, psychological, and social functioning and are vastly overrepresented in intensive, high-cost geriatric programs such as home-based primary care and nursing home facilities. The challenges of treating this growing population and the associated high costs will have profound economic and ethical implications for VHA. Ethical and legal mandates behoove the VHA to provide evidence-based, recovery-oriented care, supporting the preferences of these individuals to reside in non-institutional settings and preserve their independence and functioning. Despite repeated urgent calls for greater attention to this vulnerable population, there are few interventions targeted to prevent rapid functional decline and premature institutionalization in this group.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Over the next two decades, Veterans with psychotic disorders (i.e., schizophrenia spectrum disorders and affective psychoses) will age into older adulthood in unprecedented numbers (1-2). The aging process has a particularly detrimental impact on this population; older adults with psychotic disorders exhibit markedly diminished physical (5-8), cognitive (9), psychological (39), and social (10) functioning and are vastly overrepresented in intensive, high-cost geriatric programs such as home-based primary care and nursing home facilities (11-13). The challenges of treating this growing population and the associated high costs will have profound economic and ethical implications for VHA (3-4). Ethical and legal mandates behoove the VHA to provide evidence-based, recovery-oriented care, supporting the preferences of these individuals to reside in non-institutional settings and preserve their independence and functioning (4). Despite repeated urgent calls for greater attention to this vulnerable population (1-2, 4), there are few interventions targeted to prevent rapid functional decline and premature institutionalization in this group.

Structured exercise programs are highly effective in improving physical, cognitive, psychological, and social functioning in older adults (14-19). Exercise interventions also significantly benefit adults with psychotic disorders (20-22). However, older adults with psychosis exhibit low levels of physical activity and unique barriers to exercise participation, including prototypical features of psychosis (e.g., negative symptoms, medication side effects) and exacerbating features of the aging process (e.g., increased medical comorbidity, declines in musculoskeletal health). Pilot analyses I conducted provide some of the first evidence that older Veterans with psychotic disorders (n=9044) experience significantly more medical and psychosocial barriers to physical activity than their same-age peers or their younger counterparts. Strategies to empower these individuals to overcome barriers and participate in health-promoting activities, such as exercise, are sorely needed.

Peer support interventions, or interventions delivered by individuals who are similar to a patient population on some characteristic such as age or diagnosis, effectively promote engagement in health behaviors such as exercise (23-25, 28-31). Peer-delivered exercise interventions for older adults promote exercise self-efficacy, initiation and maintenance of exercise behaviors, and increased levels of general physical activity (32-35). In addition, peer support interventions delivered by individuals with a lived experience of mental illness are an effective (36-38) and integral component of recovery-oriented mental health care, and close to 900 Peer Specialists (Veterans in recovery from a mental illness) have been hired nationally as part of VA's recovery transformation (26-27). Despite the promise of peer support and urgent needs of older adults with psychosis, there are no well-specified peer support interventions that promote participation in health behaviors and are tailored to the needs of this group.

References

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2 If available, upload your applicable literature search:

Name	Created	Modified Date
References Cited_NEW_060616.pdf(0.01)	11/4/2016 9:41 AM	11/4/2016 9:41 AM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

*Aim 1: Feedback will be obtained from two panels of experts (the Veterans Advisory Panel, and an expert panel of researchers) via e-mail, phone, and/or in-person communication. Expert panelists will receive an informational sheet outlining the basic elements of consent prior to participation in this aim. (See Additional Documents).

*Aim 2: Veteran participants (n=6) will be recruited to participate in an open trial of PEER, a peer-delivered, group-based coaching intervention consisting of a 12-week intensive phase and a 12-week maintenance phase. PEER will promote participation in supervised fitness training and daily physical activity. Participants will have access to the Senior Exercise Rehabilitation Center (SERC), an exercise facility located in the Baltimore VA Annex building, which is staffed by GRECC exercise physiologists who provide supervision and oversight.

(1) Consent and screening visit (180-240 minutes): Research staff will obtain informed consent prior to any study activities. Participants will then complete a history and physical with a GRECC medical provider to determine continued eligibility. The screening will include a fasting blood draw (approximately 2 tablespoons) to measure electrolyte, hormone and cholesterol levels and to determine an average blood sugar level over the past 3 months. Screening will include exercise testing on a treadmill. During treadmill testing, electrodes will monitor heart rhythm and a facemask may be used to analyze the participant's breathing. Participants who exhibit cardiovascular abnormalities (e.g., symptomatic coronary artery disease) or uncontrolled blood sugar levels which would preclude safe exercise participation will be excluded or referred for treatment prior to inclusion. Participants will be paid $40 for the screening.

2) Veterans who meet eligibility criteria and complete informed consent may be asked to undergo tests of physical performance during the course of their participation in the study.

3) PEER Engagement Session (60 - 90 minutes): Veterans who meet eligibility criteria and provide informed consent will be assigned a peer coach and scheduled for an engagement session. In this first contact, peer coaches will provide basic education about the benefits of exercise and exercise safety and discuss the Veteran's fitness and recovery goals. PEER sessions will be audio recorded with the Veteran's permission.

4) Supervised fitness training sessions: Eligible participants will be provided an exercise prescription for 60 minutes of supervised fitness training, three times a week, tailored to their physical profiles and consistent with general exercise recommendations for older adults. They will be invited to attend the Baltimore VA SERC facility to complete their prescriptions, under the supervision of GRECC exercise physiologists, at their convenience for the duration of the 24-week trial. Additionally, for the first 12 weeks of the trial, peer coaches will invite all participants to exercise together at the SERC at a specified day and time once a week.

5) PEER group sessions (60 minutes x 12 weekly sessions): Veteran participants will be invited to attend 12 weekly PEER group sessions, led by peer coaches, which will consist of education, action planning, and goal setting regarding Gerofit participation and everyday physical activity. During PEER group sessions, participants that reach their fitness goals will have the opportunity to receive a prize for their efforts, valued at $10 or less.

6) Other support: Peer coaches will provide other support in between group sessions to promote exercise participation, such as reminder calls/prompts, throughout the 24-week trial.

7) Post-treatment in-depth interviews (60-120 minutes). Following an intensive phase of peer coaching (~12 weeks), participants will complete an in-person semi-structured audio-recorded interview assessing acceptability and perceived utility of the intensive phase of the PEER intervention. Participants will be paid $40 for their completion of this interview and it can be split into multiple appointments if needed.

8) Follow-up brief interviews (30-60 minutes). At the end of ~24 weeks, Veteran participants will be contacted by phone for an audio-recorded phone interview, assessing acceptability and perceived utility of the maintenance phase of the PEER intervention. This interview may be conducted in person if the Veteran prefers.

If a participant expresses to study staff that he or she is having difficulty attending study appointments due to lack of transportation then a bus token, or equivalent travel voucher, will be offered to the participant if available.

9) Qualitative interviews of PEER facilitators (60-120 minutes) The group facilitators will be invited to complete an optional qualitative interview about their thoughts, feelings, and experiences in training and delivering the intervention. If an eligible facilitator agrees to participate they may be invited to complete additional, optional interviews throughout the course of the study.

*Aim 3: Veteran participants (n=20) will be recruited for a pilot randomized controlled trial of PEER. All participants will have access to supervised fitness training at the SERC at the Baltimore VA Medical Center or the Loch Raven VA Medical Center. Participants will be randomized to receive group-based peer coaching (the PEER condition) or individual support from non-peer staff (the enhanced supervised fitness training condition, ESFT).

1) Consent (60 minutes): Informed consent may be completed virtually by phone/video, or in person. Research staff will obtain informed consent prior to any study activities.

2) Screening: Screening procedures will include an extensive chart review by GRECC staff and a GRECC medical provider, with sign-off on eligibility by the medical provider. Current medications, medical diagnoses, and height and weight information will be recorded from the chart. On a case-by-case basis, participants may be asked to complete a history and physical (remote or in person, 30 minutes) with a GRECC medical provider. They may also be asked to complete a fasted blood draw and/or a glucose test, at the discretion of the GRECC medical provider, to determine eligibility. The fasting blood draw (approximately 2 tablespoons) would measure electrolyte, hormone, lipid, and cholesterol levels and/or determine an average blood sugar level over the past 3 months.

2) Baseline assessment and randomization (120-180 minutes): Eligible Veterans will complete questionnaire and semi-structured interview measures of physical activity, mobility, self-efficacy, social support, psychiatric symptoms, cognition, quality of life, and/or functioning. Following completion of these assessments, participants will be randomized to the PEER condition or the ESFT condition. Participants will be paid $50 for completing the baseline assessment. The assessment can be split into multiple appointments if needed. Parts of this assessment may be completed via phone/video if meeting face-to-face is not feasible and/or if meeting face-to-face would result in a delay in gathering the data. Measures of physical activity may be repeated at an additional visit if necessary.

3) Baseline step-count measurement: After completing the informed consent and before their first individual session, participants will be asked to wear a pedometer for one week to measure their total step count. The pedometer may be provided to the participant in person or mailed to the participant's home with their permission.

4) PEER/ESFT individual sessions (60 minutes): Participants in the PEER condition will be assigned to a peer coach and scheduled for an individual session. In this first individual session, peer coaches will provide basic education about the benefits of exercise and general physical activity, exercise safety, and discuss the veteran's fitness and recovery goals. Participants in the ESFT condition will meet individually with non-peer research staff. In the first individual session for ESFT, research staff will explore potential benefits of and barriers to being physically active. Participants may complete one or more individual sessions during the course of their study participation. Individual sessions can be completed via phone/video if meeting face-to-face is not possible and/or if meeting face-to-face would cause an extended delay in the participant beginning the study.

5) Supervised fitness training sessions: Eligible participants will be provided an exercise prescription for 60 minutes of supervised fitness training, three times a week, tailored to their physical profiles and consistent with general exercise recommendations for older adults. They will be invited to attend the Baltimore VA or Loch Raven VA SERC facilities to complete their prescriptions, under the supervision of GRECC exercise physiologists, by appointment, for the duration of the 24-week trial. Physiologists will complete tests of physical function during select gym visits (baseline, 12 weeks, and 24 weeks post-randomization).

6) PEER group sessions (50-60 minutes): The procedures for this are the same as for Aim 2. Only those in the PEER condition attend PEER group sessions. PEER group sessions may be delivered via phone/video.

7) Other support: The procedures for this are the same as for Aim 2, except that for those randomized into the ESFT condition, support will be provided by non-peer staff.

8) PEER graduate groups (50-60 minutes): Optional monthly graduate groups will be offered to participants in the PEER condition once they complete the weekly groups described above. The group will be facilitated by the same peer support specialist(s) who lead the PEER group to provide extra support for veterans during the second phase of the PEER intervention. PEER graduate groups may be delivered via phone/video. Once the veteran completes the second phase of the intervention they will no longer be able to attend the graduate groups.

9) Time point 2 assessments (120-180 minutes): At time point 2 (~12 weeks after randomization), Veterans will complete another set of assessments including questionnaire/interview measures of physical activity, mobility, self-efficacy, social support, psychiatric symptoms, cognition, quality of life, and/or functioning. Veterans will be paid $50 for these assessments and it can be split into multiple appointments if needed. Parts of this assessment may be completed via phone if meeting face-to-face is not feasible and/or if meeting face-to-face would result in a delay in gathering the data. Measures of physical activity may be repeated at an additional visit if necessary.

10) Time point 2 step-count measurement: At time point 2 (~12 weeks after randomization), Veterans will again be asked to wear a pedometer for one week to measure weekly step-counts. The pedometer may provided to the participant in person or mailed to the participant's home with their permission.

11) Time point 3 assessments (60-120 minutes): At time point 3 (~24 weeks after randomization), Veterans will complete another set of assessments, including questionnaire/interview measures of physical activity, mobility, self-efficacy, social support, psychiatric symptoms, cognition, quality of life, and/or functioning. Veterans will be paid $50 for these assessments and it can be split into multiple appointments if needed. Parts of this assessment may be completed via phone if meeting face-to-face is not feasible and/or if meeting face-to-face would result in a delay in gathering the data. Measures of physical activity may be repeated at an additional visit if necessary.

12) Time point 3 step-count measurement: At time point 3 (~24 weeks after randomization), Veterans will again be asked to wear a pedometer for one week to measure weekly step-counts. The pedometer may provided to the participant in person or mailed to the participant's home with their permission.

13) In-depth qualitative interview (60-120 minutes): After completion of the 24 week randomized controlled trial, participants will be invited to complete in-depth individual interviews regarding their experiences with the PEER/ESFT interventions, and with supervised fitness training. Veterans will be paid $50 for this interview and it can be split into multiple appointments if needed. This interview can be completed in person or via phone/video if needed.

If a participant expresses to study staff they he or she is having difficulty attending study appointments due to lack of transportation then a bus token, or equivalent travel voucher, will be offered to the participant if available.

14) Qualitative interviews of PEER facilitators (60-120 minutes) The group facilitators will be invited to complete an optional qualitative interview about their thoughts, feelings, and experiences in training and delivering the intervention. If an eligible facilitator agrees to participate they may be invited to complete additional, optional interviews throughout the course of the study. These interviews may be completed in person or by phone/video.

15) Follow Up Qualitative interviews of Aim 2 and Aim 3 participants (approximately 60 minutes) Our previous participants, who have given us permission to contact them after their study participation, will be invited to complete an optional follow up qualitative interview to check in with them regarding their health and physical activity. These interviews may be in person or by phone/video.

*Aim 4: Veteran participants (n=18) will be recruited to complete a battery of assessments of height/weight, symptoms, physical activity, cognition, and functioning. Research staff will obtain informed consent prior to any study activities. Veterans will complete the same questionnaire and semi-structured interview measures as the baseline assessments for participants in Aim 3 (180-240 minutes). The assessments will include measures of physical function, physical activity, mobility, self-efficacy, social support, psychiatric symptoms, cognition, quality of life, and/or functioning. There will also be clinician-rated measures of everyday functioning included in the assessment battery, to be completed by the veteran's primary mental health provider. Research staff will obtain informed consent prior to any study activities. We will also be conducting a chart review in order to document current medications, medical diagnoses, and participant's height and weight if needed. Veterans will be paid $45 for completing these assessments and it can be split into multiple sessions if needed.

Documents for this study include:

1. Documents with identifiable information: Informed Consent Forms (ICF's), HIPAA Authorization forms, Evaluation to sign ICF, Exercise prescriptions, exercise test reports
2. Coded data: (2a) hard copies of interviews, surveys, and assessments and (2b) coded electronic data
3. CDs/DVDs/Electronic audio recordings

(1) Documents with identifiable information

ICF's, HIPAA Authorization Forms and the Evaluation to Sign Consent contain participants' names but not their project ID number. If these documents are collected at the VA they are kept in a separate locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201). If the consent visit is completed remotely, we will save any consent-related documents to our study restricted access folder to ensure this electronic information is protected from unauthorized access.

Exercise prescriptions and exercise test reports contain participants' names but not their project ID number. Exercise prescriptions are kept in a separate locked cabinet in a locked office at the VA site the participant attends for exercise training (VA Annex, 209 W. Fayette Street, Baltimore, MD 21201 or 3900 Loch Raven Blvd, Baltimore, MD 21218). Exercise testing and reports to determine study eligibility will be completed and temporarily stored at the GRECC offices in the Baltimore VA Medical Center in locked cabinets in a locked office (10 N. Greene St, 4th floor, Baltimore, MD 21201). Once the reports are complete and an eligibility determination is made, the reports will be transported by hand in a locked bag to the MIRECC offices (VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201) and stored in a locked cabinet in a locked office.

2a) Coded data, hard copies

All hard copies of coded research assessments will be stored in a locked cabinet in a locked office in the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201), or will be transported by hand in a locked bag and stored in a locked cabinet in a locked office in the University of Maryland, Division of Psychiatric Services Research for data entry. Once data is entered, it will be returned to VA for final storage. Data collected remotely will be securely stored in a locked HIPAA bag and transported to the VA as soon as possible. Access to hard copies of coded research assessments will be limited to only study staff listed on this protocol.

2b) Coded electronic data

The CTRIC team will create a REDCap database to the PIs specifications. Paper copies of coded research data (assessments) will be entered into, stored and managed by a VA REDCap database. REDCap is a free, secure Web application installed on the VA intranet that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable VA users to quickly develop surveys and databases from conception to production on the web without additional software requirements. This tool helps VA researchers enter, store, and manage their project data in a systematic manner. This service is provided through the VA Information Resource Center (VIReC) that develops resources for and provides guidance to VA researchers using data. The VIReC's staff, scientists, and advisors include database

and informatics experts, research methodologists, and experts for various database content areas. The database is configured to use FIPS 140-2 encryption available in the underlying infrastructure to protect sensitive data at rest. In addition, the information system and its dependencies have gone through the VA Assessment and Authorization (A&A) process to evaluate any associated risks and was granted an Authorization to Operate (ATO) as indicated. Primary data are stored at the secure VA Austin Information Technology Center (AITC), located in Austin, Texas on a VINCI Server. Data are backed up nightly and REDCap provides detailed audit trails and specific controls over user rights. Users must have a VA account to log in to REDCap.

3) CDs/DVDs/electronic audio/video recordings

Audio/Video Recordings may be viewed for supervision purposes by the PI and the other members of the research staff that administer these interviews. All CD's, DVD's, and recorders containing audio/video recordings will be collected at the VA and/or remotely if needed. Data collected at the VA will be stored in a locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201). Data collected remotely, if meeting face-to-face is not possible, will be securely stored in a locked HIPAA bag and transported to the VA as soon as possible. Electronic audio files will be stored securely behind the VA Firewall. All audio/video recordings will be identified by codes only, and will not contain participants' names. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

N/A

3 * Describe the duration of an individual participant's participation in the study:

*Aim 1: Panelists will be involved in providing feedback on the intervention for one year.

*Aim 2 (n=6): Participants engage in the following study activities over ~30 weeks. Consent, screening, and assessments will be spread over multiple visits as needed.
Consent and screening visit- 180-240 minutes
PEER engagement session- 60-90 minutes
Supervised fitness training sessions- ~60 minutes/day, three days/week, for 24 weeks
PEER group sessions- ~60 minutes/week for 12 weeks
In-person qualitative interview- 60-120 minutes
Follow-up phone interview- 30-60 minutes

*Aim 3 (n=20): Participants engage in the following study activities over ~30 weeks. Consent, screening, and assessments will be spread over multiple visits as needed.
Consent- 60 minutes
History and physical and blood draw (as needed)- 60 minutes
Baseline assessment and randomization- 120-180 minutes
PEER/ESFT individual sessions- 60-120 minutes
Gerofit supervised fitness training sessions- ~60 minutes/day, three days/week, for 24 weeks
PEER group sessions- ~60 minutes/week for first 12 weeks of study participation
PEER graduate groups (optional) - ~60 minutes/month for second 12 weeks of study participation
Time point 2 assessments- 120-180 minutes
Time point 3 assessments - 60-120 minutes

Qualitative interview (n=15-20)- 60-120 minutes

Follow-up qualitative interview for Aim 2 and Aim 3 participants - approximately 60 minutes

Aim 4 (n=18):
180-240 minutes for consent and assessment battery

4 * Describe the amount of time it will take to complete the entire study:

Aim 1: 1 year
Aim 2: 1 year and 3 months
Aims 3 and 4: 2 years and 9 months

Total duration: 5 years

5 * Describe any additional participant requirements:

N/A

ID: VIEW4E0280585B400
Name: v2_Study Procedures

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

For the open trial (Aim 2), we aim to recruit 6 older Veterans with psychotic disorders to establish acceptability and perceived utility of the PEER intervention.

For the pilot randomized controlled trial (Aim 3), we aim to recruit 20 older Veterans with psychotic disorders to establish feasibility and preliminary efficacy of the PEER intervention compared to the ESFT condition. All participants (n=20) will be invited to participate in qualitative interviews.

For Aim 4, we aim to recruit 18 older Veterans with psychotic disorders to complete in-depth assessments of health and functioning.

Across Aims 2, 3, and 4, following initial chart screening, we estimate that we will enroll 60 participants. With these 60 participants, additional screening procedures will be conducted, and some participants will no longer be eligible. Then we will have final sample sizes of 6 for Aim 2, 20 for Aim 3, and 18 for Aim 4.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

Aim 2: We will conduct qualitative analysis of in-person and phone interview data. Interview audio files will be transcribed verbatim. After transcription, participants' comments will be compiled to summarize acceptability and perceived utility of each of the components of the PEER intervention.

Aim 3 (quantitative):

PEER intervention feasibility will be measured using descriptive statistics, including:
(a) rates of engagement (# who attended at least three PEER group sessions after the engagement session divided by # randomized to PEER)
(b) attendance of group sessions (percent of participants who engaged in PEER who attend 50% or more of PEER group sessions)
(c) treatment dropout rates (# who dropped out prior to completing the intervention divided by # who engaged)

PEER intervention preliminary efficacy will be tested by comparing the PEER condition and the ESFT condition on a number of outcomes, including:
(a) Attendance of supervised fitness training sessions, i.e., the number of times participants attended supervised fitness training sessions, including both peer-attended and independent visits. Group mean counts of attendance at the fitness training sessions during the intensive period will be compared using a Poisson or Negative Binomial regression model with treatment condition as the primary independent variable.
(b) Ambulatory physical activity, i.e., total number of step-counts for one week, measured by pedometer. We will use an ANCOVA model to compare mean step-count at TP2, adjusting for baseline measurement (TP1).
(c) Maximal aerobic capacity, measured by Graded Exercise Treadmill Test, using ANCOVA in the same way as in (b).
(d) Other outcomes, including self-reported physical activity, MPPT, 6-MWD, and VR-36 Physical Component Score.
(e) We will assess the maintenance of treatment effects at TP3 by comparing group means at TP3 using a two-time-point repeated outcomes model (TP2 and TP3) while continuing to adjust for baseline value.
(f) Exploratory analyses will be conducted to identify potential mediators and moderators of treatment.

Aim 3 (qualitative): We will conduct qualitative analysis of interview data. Interview audio files will be transcribed verbatim. Data from qualitative interviews will be used to develop a deeper understanding of the barriers/facilitators to health behavior change experienced by older Veterans with psychosis. Data will also be used to add context to quantitative findings, particularly with questions related to "how" and "why" the intervention did or did not work.

Aim 4 (quantitative): We will use blocked entry regression analyses to examine relative contributions of RBANS score, PANSS negative symptom subscale, BDI total, UPSA-Brief score, and MPPT score to the prediction of each of the SLOF domains. Age, gender, BMI, and Charlson Comorbidity Index will be entered as covariates.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

In Aims 2 and 3, participants will undergo a physical, exercise tests, and/or tests of physical function. Participants will be advised of findings from the screening physicals and exercise tests that have a direct effect on their health. With a participant's permission, these results will be shared with his/her doctor. These findings may be shared through a note or consult in the electronic medical record. The screening may include a blood draw. Lab results will be posted in participants' electronic medical records.

For Aims 2, 3, and 4, if clinically indicated during study participation, research staff may ask permission from participants to speak with members of their VA treatment team or with other VA treatment providers, to facilitate clinically appropriate referrals and care coordination.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [x] **Key informant or semi-structured individual interviews**
- [x] **Focus groups or semi-structured group discussions**
- [x] **Audio or video recording/photographing**
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [x] **Psychosocial or behavioral interventions**
- [x] **Neuropsychological or psychophysiological testing**
- [ ] Deception
- [x] **Other psychosocial or behavioral procedures**

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

HP-00072447 Surveys/Questionnaires_V2

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:

MIRECC Demographic Form
International Physical Activity Questionnaire (IPAQ)
Exercise Self-Efficacy Scale (EXSE)
Barriers Self-Efficacy Scale
Social Support for Exercise Survey
Veterans RAND 36-Item Health Survey (VR-36)
World Health Organization Disability Assessment Schedule 2.0 (Clinician-Rated WHO-DAS)
Life Space Questionnaire (LSQ)
Geriatric Depression Scale- Long Form (GDS)
Level of Functioning Assessment (SLOF)
World Health Organization Disability Assessment Schedule (WHO-DAS)
BMI Form

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
BMI Form(0.01)	11/8/2019 12:10 PM	11/8/2019 12:10 PM
WHO-DAS 2.0(0.03)	10/24/2016 12:22 PM	7/30/2019 2:34 PM
MIRECC Demographic Form 5.1.2019(0.02)	10/24/2016 12:21 PM	5/1/2019 3:06 PM
WHO-DAS(0.01)	1/24/2019 8:23 AM	1/24/2019 8:23 AM
GDS Long Form(0.01)	10/18/2018 1:03 PM	10/18/2018 1:03 PM
Level of Functioning Assessment (SLOF)(0.01)	9/14/2018 3:17 PM	9/14/2018 3:17 PM
LSQ(0.01)	9/12/2018 3:35 PM	9/12/2018 3:35 PM
VR-36(0.01)	10/24/2016 12:22 PM	10/24/2016 12:22 PM
Social Support for Exercise(0.01)	10/24/2016 12:22 PM	10/24/2016 12:22 PM
Barriers Self-Efficacy(0.01)	10/24/2016 12:22 PM	10/24/2016 12:22 PM
EXSE(0.01)	10/24/2016 12:21 PM	10/24/2016 12:21 PM
IPAQ(0.01)	10/24/2016 12:21 PM	10/24/2016 12:21 PM

3 * What is the total length of time that each survey is expected to take?

MIRECC Demographic Form- 5 minutes
International Physical Activity Questionnaire- 15 minutes
Exercise Self-Efficacy Scale- 5 minutes
Barriers Self-Efficacy Scale- 5 minutes
Social Support for Exercise Survey- 5 minutes
Veterans RAND 36-Item Health Survey- 15 minutes
Life Space Questionnaire - 5 minutes
Geriatric Depression Scale- Long Form - 5 minutes
World Health Organization Disability Assessment Schedule - 10 minutes
BMI Form - 5 minutes

Clinician-rated measure
Level of Functioning Assessment - 15 minutes
World Health Organization Disability Assessment Schedule 2.0 (clinician rated) - 5 minutes

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

○ Yes ● **No**

5 * Do any questions elicit information related to the potential for harm to self or others?

● **Yes** ○ No

5.1 If Yes, what procedures are in place to assure safety?

The MIRECC has established good clinical practice guideline SOPs on how, when, and what to communicate around safety issues. Should a mental health crisis arise, several procedures will be followed. First, the research staff will notify one of the study investigators. Second, a study investigator or trained research staff will assess the participant further to determine the presence of an intent or plan to harm self. Third, the participant's mental health clinician will be contacted, if possible. The mental health clinician, who typically has a long-standing relationship with the participant, will help determine whether further action is needed. Fourth, if determined to be necessary, a study investigator or a member of the research team will escort the participant to the University of Maryland ER or the VA Medical Center ER for further

psychiatric assessment if possible. If safety concerns arise during a phone assessment, steps 1-3 above will be completed as per regular study procedures and if needed local authorities will be contacted to ensure participant safety.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

HP-00072447 Interviews_V2

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

● **Yes** ○ No

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
Follow Up Interview Script(0.01)	6/9/2020 3:11 PM	6/9/2020 3:11 PM
BPRS Manual(0.01)	10/18/2018 1:05 PM	10/18/2018 1:05 PM
BPRS Score Sheet(0.01)	10/18/2018 1:05 PM	10/18/2018 1:05 PM
BPRS(0.02)	10/24/2016 12:36 PM	10/18/2018 1:02 PM
PEER Facilitator Interview Guide.docx(0.01)	10/18/2018 11:45 AM	10/18/2018 11:45 AM
Qualitative Interview Script.docx(0.01)	10/24/2016 1:38 PM	10/24/2016 1:38 PM

3 * What is the individual duration of each interview and what is the entire duration of the interviews?

In-depth qualitative interviews (Aims 2 and 3)- 60-120 minutes
Brief qualitative interview (Aim 2 only) - 30-60 minutes
BPRS (Aim 3 and 4)- 30 minutes
Follow Up Qualitative Interviews - approximately 60 minutes

4 * How will the interview responses be recorded and by whom?

Aim 2-3 Qualitative Interviews & Follow Up Interviews - These interviews will be audio recorded by the research staff conducting the interviews.

BPRS- Research staff conducting the interview will record responses in writing on the BPRS interview form.

5 * Do any questions elicit information related to the potential for harm to self or others?

● **Yes** ○ No

5.1 If Yes, what procedures are in place to assure safety?

The MIRECC has established good clinical practice guideline SOPs on how, when, and what to communicate around safety issues. Should a mental health crisis arise, several procedures will be followed. First, the research staff will notify one of the study investigators. Second, a study investigator or trained research staff will assess the participant further to determine the presence of an intent or plan to harm self. Third, the participant's mental health clinician will be contacted, if possible. The mental health clinician, who typically has a long-standing relationship with the participant, will help determine whether further action is needed. Fourth, if determined to be necessary, a study investigator or a member of the research team will escort the participant to the University of Maryland ER or the VA Medical Center ER for further psychiatric assessment if possible. If safety concerns arise during a phone assessment, steps 1-3 above will be completed as per regular study procedures and if needed local authorities will be contacted to ensure participant safety.

ID: VIEW4E0947A633C00
Name: v2_Interviews

HP-00072447 Focus Groups_V2

Focus Groups

You indicated that this study involves focus groups or semi-structured group discussions.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

○ Yes ● **No**

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
SemiStructuredDiscussion.docx(0.01)	12/30/2016 10:06 AM	12/30/2016 10:06 AM

3 * How much time are the groups expected to require?

Approximately 6 meetings per panel, approximately 1 hour each.

4 * How will the data be recorded?

In each meeting, detailed minutes will be taken. Following the meeting, these minutes will be circulated to all the panelists, who will be asked to respond with corrections or additions.

5 * Do any questions elicit information related to the potential for harm to self or others?

○ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E094A8F91800
Name: v2_Focus Groups

HP-00072447

Audio or Video Recording_V2

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1

* Indicate the type of recording (check all that apply):

- [x] **Video**
- [x] **Audio**
- [ ] Still Photo
- [ ] Other

1.1

If Other, specify:

2

* What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)

We are audio recording qualitative interviews for the purpose of capturing main themes and perspective of Veterans.

We are audio/video recording the individual/group sessions in order to provide feedback and train/supervise study staff on the intervention.

We are audio/video recording select assessments in Aims 3 and 4 to provide feedback, training, and supervision for study staff completing the assessments.

3

* Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?

(●) **Yes** ( ) No

4

* How will individuals' identities be protected?

Audio/video recorders, CD's, or DVDs containing audio/video recordings will not be labeled with any identifying information and will be kept in a locked storage area behind a locked door. CD's and DVD's will be encrypted using VA installed encryption software. If audio files are stored electronically, they will be stored behind the VA firewall in a restricted access folder.

Audio recordings of interviews will be transcribed by an outside VA-approved transcription agency, so as to not have the actual audio recording be the only copy of this research data. Electronic files of audio recordings will be electronically uploaded to our VA-Approved Transcription agency's website (encrypted) in order for them to transcribe the interviews.

ID: VIEW4E094C128C800
Name: v2_Audio or Video Recording / Photographs

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

1 * Describe the intervention (duration, number of sessions, focus, etc.):

Supervised fitness training sessions:

In both Aims 2 and 3, all participants will be invited to attend the SERC at their convenience, by appointment, during the facility's hours, under the supervision of exercise physiologists, for the duration of the 24-week trial. If a participant expresses to study staff he or she is having difficulty attending study appointments due to lack of transportation then a bus token, or equivalent travel voucher, will be offered to the participant if available. All participants will receive an exercise prescription that fits within the following parameters: 60 minutes of supervised fitness training, three times a week consistent with American College of Sports Medicine recommendations. Prescriptions will include 30 minutes of moderate intensity aerobic exercise. The specific modality of exercise (i.e., treadmill, elliptical trainer, upright or recumbent cycle ergometer, or recumbent stepper) and intensity of those exercises will be tailored to the ability, fitness and strength levels of the individual so that exercise is prescribed at the same relative intensity for each participant, beginning with an intensity of 50% maximal aerobic capacity (VO2max) for 20-30 minutes for the first two weeks, and progressing as tolerated to 60-70% VO2max. Exercise intensity, prescribed as a target heart rate range, may be monitored using chest-strap heart rate monitors when possible. Prescriptions will also include approximately 20 minutes of strength training of the major muscle groups of the upper and lower extremities (leg press, leg extension, leg curl, chest press, row) on Keiser pneumatic strength training equipment (Keiser, Fresno, CA). Participants will perform 2 sets of approximately 10 repetitions of each exercise. All weights will be initially started at the maximum weight a participant can lift for approximately 10-12 repetitions. Weight will be progressed in a step-wise fashion; when a participant can lift a specific weight for more than 15 repetitions, weight will be increased to the point where the subject can only repeat approximately 10-12 repetitions. Finally, prescriptions will include approximately 10 minutes of flexibility exercises during the exercise session as appropriate. Sessions will be monitored by trained exercise physiologists. Blood pressure will be assessed before, during, and after each session; heart rate will be assessed when possible. For participants with T2DM/taking medication for T2DM, blood glucose levels will be monitored before, during, and after exercise sessions as needed. Snacks and rapidly acting carbohydrate are available if needed. If necessary, subjects may be advised to speak with their physicians about altering the dosage or timing of their medications to ensure safety and avoid hypoglycemia during exercise sessions.

Peer Education on Exercise for Recovery (PEER):

In Aim 2, all participants will participate in PEER. In Aim 3, half the participants will be randomized to participate in PEER. PEER is a peer-delivered, group-based coaching intervention, which will promote participation in supervised fitness training and everyday physical activity. PEER will consist of a 12-week intensive phase and a 12-week maintenance phase. The intensive phase will consist of one-on-one individual sessions with a peer coach, 12 weekly PEER group sessions led by a peer coach with a focus on education/goal-setting/action planning, and other support such as phone call reminders/prompts from the peer coach. The 12-week maintenance phase will include continued, stepped down support from the peer coach. All components of PEER may be delivered by phone/video.

Enhanced Supervised Fitness Training (ESFT; Aim 3 only):

In Aim 3, half the participants will be randomized to participate in ESFT. ESFT will provide individual support from non-peer research staff, to promote participation in supervised fitness training and everyday physical activity. ESFT will consist of individual session(s) and other support such as phone call reminders/prompts from a non-peer research staff member, over a 24-week period. All components of ESFT may be delivered by phone/video.

ID: VIEW4E0BC12A9F800
Name: v2_Behavioral Interventions

HP-00072447 Testing_V2

Testing

You indicated that this study involves neuropsychological or psychophysiological testing.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all of the tests to be used in the study, including both standardized and non-standardized assessments:
Repeatable Battery of Assessment for Neuropsychological Status (RBANS)
TRAILS A (TMT A)
UCSD Performance-Based Skills Assessment - Brief Version (UPSA-B)

2 * Describe procedures related to all testing:
The RBANS is a comprehensive neuropsychological screening battery for individuals with SMI. In Aim 3 the pilot randomized controlled trial, the RBANS will be completed at baseline and time point 2. In Aim 4 it will be completed one time. It will take about 30 minutes to complete. For participants completing this assessment by phone/video, a limited set of subtests will be completed.

The TRAILS A is a neuropsychological measure that will obtain a brief and well-validated measure of processing speed. It will be used in Aim 3 and Aim 4. Participants will complete the trail making test for part A and be scored on the length of time it takes them to complete. This assessment will not be completed for individuals completing assessments via phone/video.

The UPSA-B is a measure of functional capacity and assesses skills involved in community tasks. This typically takes around 15 minutes to complete and will be used in Aim 3 and 4. This assessment will not be completed for individuals completing assessments via phone/video.

3 * Upload relevant testing materials:

Name	Created	Modified Date
UPSA B(0.01)	10/18/2018 1:21 PM	10/18/2018 1:21 PM
TRAILS A(0.01)	10/18/2018 1:14 PM	10/18/2018 1:14 PM
RBANS summary.doc(0.01)	10/24/2016 2:50 PM	10/24/2016 2:50 PM

4 * What is the individual duration of each test and what is the entire duration of all tests?
RBANS - 30 minutes
TRAILS A - 5 minutes
UPSA-B - 15 minutes

5 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)
○ Yes ● **No**

6 * Do any questions elicit information related to the potential for harm to self or others?
○ Yes ● **No**

6.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0BC1E3C2800
Name: v2_Testing

HP-00072447 Other_V2

Other Psychosocial or Behavioral Procedures

You indicated that this study involves other psychosocial or behavioral procedures.

1 * Describe the other psychosocial or behavioral procedures that will be involved in the research:

1.) Modified Physical Performance Test (MPPT). The MPPT is a nine-item standardized test which provides a total score used to identify frailty and mobility dysfunction in older individuals. Below is an excerpt from an article by Brown and colleagues (2000) with a description of each of the nine items:
1. Book lift. An approximately 7-lb book is lifted from waist height to a shelf approximately 12 inches above shoulder level. Scores are based on the time required to complete the task.
2. Put on and take off a coat. Subjects put on and take off a standard lab coat of appropriate size as quickly as able. Scores are based on the time required to complete this item.
3. Pick up pen. Subjects pick up as quickly as possible a pen that is located 12 inches in front of the foot. Scores are based on the time required to complete the task.
4. Chair rise. Subjects sit in a chair that has a seat height of 16 inches. They then stand fully and sit back down, without using the hands, five times, as quickly as possible.
5. Turn 360. Participants turn both clockwise and counterclockwise quickly but safely. They are subjectively graded on steadiness and ability to produce continuous turning movement.
6. 50-ft. and 4 m walks. Subjects walk in a straight line, turn, and return to the initial starting place as quickly as possible, safely.
7. One flight of stairs. The time required to ascend 10 steps.
8. Four flights of stairs. Participants climb four flights of stairs. One point is given for each flight of stairs completed.
9. Progressive Romberg test. Subjects are scored according to their ability to maintain a reduced base of support: feet together, semitandem, and full tandem, for a maximum of 10 seconds.

2.) Six Minute Walk Distance (6-MWD). During the 6-MWD test, participants will be asked to walk as far as possible in 6 minutes; this is a widely-used measure of physical function with evidence of reliability and validity in adults with psychosis (Vancampfort et al., 2011).

3.) Measuring step-counts with pedometer. In Aim 3, ambulatory physical activity will be measured using the Yamax Digi-Walker SW-701 pedometer or a similar model (YamaxUSA, San Antonio, TX). Daily and total step counts for the week will be recorded. Participants will be queried about whether they were able to wear them as instructed for the full seven days. They will be trained on the use of pedometers. Aim 3 participants will wear the pedometer for seven days at baseline, time point 2, and time point 3.

2 Upload any relevant materials:

Name	Created	Modified Date
SIX MINUTE WALK DISTANCE.docx(0.01)	10/24/2016 2:52 PM	10/24/2016 2:52 PM
MPPT_ScoringSheet.pdf(0.01)	10/24/2016 2:52 PM	10/24/2016 2:52 PM
MPPT_Instructions.docx(0.01)	10/24/2016 2:52 PM	10/24/2016 2:52 PM

3 * What is the individual duration of each procedure and what is the entire duration of all procedures?

MPPT: ~30 minutes
6-MWD: ~10 minutes
Pedometer: ~5 minutes to train participants on how to use it

4 * Are any of the procedures (or do any of the procedures elicit information) likely to cause discomfort in participants or cause harm?

● **Yes** ○ No

4.1 If Yes, what procedures are in place to assure safety?

For MPPT and 6-MWD:
There is a slight risk that participants will fall, experience leg claudication pain, chest pain, or become short of breath or dizzy during these tests. Participants will be asked to inform the research staff of any symptoms they experience during these assessments, and will be allowed to take breaks or stop assessment procedures as needed. Trained study personnel will be administering these tests. Study staff trained in CPR will administer these tests. Assessments will take place in a facility where emergency medications and resuscitation equipment are available.

ID: VIEW4E0BC6EF1E800
Name: v2_Other Psychosocial or Behavioral Procedures

HP-00072447

Sample Collection_Analysis_V2

Sample Collection/Analysis

You indicated on the "Type of Research" page that your study involves a sample (specimen) collection and/or analysis.

1 * What type of samples will be involved in this study? (Check all that apply)

- [x] **Prospective (will be collected)**
- [ ] Existing (previously collected at the time of initial IRB submission)

2 * Will genetic analysis/testing be done on any of the samples?

○ Yes ● **No**

3 * Will this study involve banking of samples (storing for future research use)?

○ Yes ● **No**

4 * What is the purpose of the sample collection and/or analysis?

Verification of eligibility criteria, as needed on a case by case basis

5 * Is there the possibility that cell lines will be developed with any of the samples?

○ Yes ● **No**

6 * Will the samples be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

6.1 If Yes, give name(s) and affiliation(s):

7 * Will the sample material be sold or given to any third parties?

○ Yes ● **No**

7.1 If Yes, give name(s) and address(es):

ID: VIEW4E0E1A4B80000
Name: v2_Sample Collection/Analysis

HP-00072447 Prospective Samples_V2

Prospective Samples

You indicated that the study involves collection of prospective samples (specimens).

1 * What type of sample will be collected? (Check all that apply)

- [x] **Blood**
- [ ] Bone Marrow Aspirate/Biopsy
- [ ] Cerebrospinal Fluid
- [ ] Saliva
- [ ] Skin
- [ ] Sputum
- [ ] Stool
- [ ] Tissue
- [ ] Tumor
- [ ] Urine
- [ ] Other

1.1 If Other, specify:

2 For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subject's entire participation time:
A one time sample of approximately 2 tablespoons at a medical screening visit, if determined to be necessary by a medical provider to confirm eligibility

3 * What type of samples will be collected? (Check all that apply)

- [x] **Samples obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study**
- [ ] Samples obtained specifically for research purposes-additional taken during a clinical procedure
- [ ] Leftover samples that were obtained for clinical purposes (no additional research procedures required)
- [ ] Commercial (for profit) samples
- [ ] Other

3.1 If Other, specify:

4 * How are these samples labeled? For example, do they contain name, initials, dates, Social Security number, medical record number, or other unique code?
Tubes will be labeled with full name, full social security number, date, and lab order number.

5 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?
○ Yes ● **No**

6 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?
○ Yes ● **No**

7 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):
Samples will be destroyed after clinical tests are run.

8 * Will the samples be destroyed after the study is over?
● **Yes** ○ No

8.1 If No, describe how the samples will be stored, where they will be stored, and for how long.

ID: VIEW4E0E257D60C00
Name: v2_Prospective Samples

HP-00072447

Data Collection_Record_V2

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- ☐ Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- ☑ **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

HP-00072447 Prospective Data_V2

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [ ] Other

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
Medications, mental health diagnosis, medical conditions, and height/weight

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

HP-00072447

Clinical Trial Registration_V2

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

● **Yes** ○ No

2 * Has this trial been registered?

● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

HP-00072447

Clinical Trial Registration Info_V2

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?

(●) **Yes** ( ) No

2 If no, was this trial registered on a site other than clinicaltrials.gov?

( ) Yes ( ) No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number

NCT02958007

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
2000

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
60

Worldwide - the number being enrolled total at all sites (including local enrollment):
60

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect

- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

● **Yes** ○ No

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

We are excluding individuals younger than 50 years of age, because this study focuses on the unique needs of older adults with psychotic disorders.

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [x] **Employees or Lab Personnel**
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

Vulnerable Populations - Employees or Lab Personnel

You indicated that employees or lab personnel are included in this study.

1 * Describe how you will ensure particiption in this research will not affect employment and prevent undue influence:

In Aim 1, some expert panelists may be VA employees. In Aims 2, 3, and 4 we are not specifically recruiting VA employees, however, it is possible that a VA employee could meet eligibility criteria for this study. In Aims 2 and 3, we will be interviewing peer interventionists, who are VA employees. There will be no specific risks associated with study participation for Employees or Lab Personnel. Informed consent will be obtained and research assessments conducted in the same manner as for other participants. Employees will be told that their participation in the study is completely voluntary. Employees will also be told that their employment status will not be affected by their decision to participate or not to participate in this study.

ID: VIEW4E0E5192BA800
Name: v2_Vulnerable Populations - Employees or Lab Personnel

HP-00072447 Eligibility_V2

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

● Yes ○ No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
Eligibility checklist for Aim 3 Updated.docx(0.01)	1/12/2021 3:47 PM	1/12/2021 3:47 PM
Eligibility checklist aim 4(0.03)	8/20/2018 2:28 PM	11/5/2019 8:44 AM
Eligibility checklist for facilitators(0.01)	9/14/2018 3:48 PM	9/14/2018 3:48 PM

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

Number	Criteria
There are no items to display	

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

Number	Criteria
There are no items to display	

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00072447_22 v1-12-2021-1610484513374(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

HP-00072447 Recruitment_V2

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):

Veterans will be recruited for this study from clinics in the VAMHCS.

Potential participants will be identified by several methods: (1) CPRS chart review and screening via use of a partial HIPAA waiver, (2) VA clinician referrals of participants who meet inclusion criteria and who might be interested in participating, (3) Self referrals by participants who hear about the study and are interested in participating or who have participated in other MIRECC studies and have indicated a willingness to be contacted for studies in the future, (4) Self-referral via IRB approved study flyer, and (5) Self-referral via MIRECC Matters newsletter.

Participants will be screened for eligibility via CPRS chart review. For Aims 2 and 3 study staff will then contact a VA treatment team member to inform whether a potentially eligible participant is clinically stable enough to participate in the study and can be contacted for recruitment. This will help avoid approaching people who may be in crisis or may not be able to comprehend the study procedures, risks, and benefits.

Per VA requirements, initial contact with Veterans will be made in person or by letter prior to any telephone contact. Specifically, we will approach individuals before or after their VA appointments.

We may also send out a letter to potential participants to see if they are interested in participating in the study. In this letter, they will be given contact information for the study staff as well as a pre-stamped postcard to mail back to indicate their interest or lack of interest in the study. If after a few days, we do not hear from them, a follow-up phone call may be made to ensure the potential participant received the mailing. This follow-up phone call is mentioned in the mailing, so that potential participants will not be caught off guard when they receive a call from study staff.

VA Staff Participants:
Group facilitators who are VA staff members will be recruited for this study. We will invite PEER group facilitators to complete optional qualitative interviews about their experiences training for and delivering the intervention. Study staff will first call or email staff members, using their VA contact information to assess whether they meet eligibility criteria. If so, study staff will provide a brief description of the study to assess the facilitator's interest in participating in the study. Employees will also be told that their employment status will not be affected by their decision to participate or not to participate in this study. If the eligible facilitator expresses interest, the staff member will schedule a date/time to meet in person to obtain written informed consent. No PHI will be collected from the staff participants but they will be given an NOPP for their records and will sign an NOPP acknowledgement form to be filed with their consent paperwork.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Participants will be told that their participation is completely voluntary and that they can choose to stop their participation at any time without any negative consequences.

Employees will also be told that their employment status will not be affected by their decision to participate or not to participate in this study.

During consent, the individual conducting the informed consent will assess competency to understand and sign the consent form by asking the participant a set of IRB-approved questions. (See "Evaluation" in Additional Documents). If the participant is unable to answer the questions correctly, the research staff member will review aspects of the study that the participant did not understand. If the participant cannot answer them a second time, he or she will be judged as not competent to give consent, and he or she will not be included in the study.

Our research team has extensive experience recruiting and obtaining informed consent from participants with serious mental illnesses. Research staff is trained to recognize symptoms of serious mental illness and cognitive impairment that could undermine the ability to provide informed consent.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Updated Baltimore Postcard.doc(0.02)	10/24/2016 4:28 PM	2/22/2018 9:03 AM
Updated recruitment Letter.docx(0.03)	10/24/2016 4:27 PM	2/22/2018 9:03 AM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00072447 Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?

(●) Yes ( ) No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio
- [x] **Internet**
- [x] **Print**
- [ ] Television
- [ ] Other

1.1.1 If Other, specify:

1.2 * Provide exact text of all proposed advertisement(s):

Flyer (Aim 2):
Interested in getting in shape? We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study of an exercise intervention.
If you qualify, you would receive FREE ACCESS to personalized fitness training at the Baltimore VA!
You could be paid up to $80 for your participation.
VISN 5 Mental Illness Research Education and Clinical Center
Grab a number below and call us for more details!

Flyer (Aim 3)
Interested in getting in shape? We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study of an exercise intervention.
If you qualify, you would receive free access to personalized fitness training at the VA!
You will be paid for your participation.
VISN 5 Mental Illness Research Education and Clinical Center
Grab a number below and call us for more details!
Exercise Study for Veterans
Kinnera at 443-421-8958

Handout (Aim 2):
Interested in getting in shape?
We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study of an exercise intervention.
If you qualify, you would receive FREE ACCESS to personalized fitness training at the Baltimore VA!
You could be paid up to $80 for your participation.
Questions? Need more information? Interested in participating?
Please call Sera Havrilla at 410-637-1425.
VISN 5 Mental Illness Research Education and Clinical Center

Handout (Aim 3):
Interested in getting in shape?
We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study involving exercise.
If you qualify, you would receive free access to personalized fitness training at the VA!
You will be paid for your participation.
Questions? Need more information? Interested in participating?
Please call Kinnera Atluri (443) 421-8958.
VISN 5 Mental Illness Research Education and Clinical Center

MIRECC Matters (Aim 3)
A number of investigators are conducting studies that are aimed at exploring mental illness risk factors as well as assisting Veterans in identifying, planning for, and achieving their personal recovery goals. Both approaches have many implications for mental health recovery. These studies are recruiting participants who receive mental health services within the VA Maryland Healthcare System. Below are descriptions of them, with phone numbers to call if you or someone you know receives mental health services within the VA Maryland Healthcare System and would like to learn more.

Interested in getting in shape? We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study of an exercise intervention.
If you qualify, you would receive free access to personalized fitness training at the VA!
You will be paid for your participation.
Please call Kinnera Atluri at 443-421-8958 if you are interested!

MIRECC Matters (Aim 4)
A number of investigators are conducting studies that are aimed at exploring mental illness risk factors as well as assisting Veterans in identifying, planning for, and achieving their personal recovery goals. Both approaches have many implications for mental health recovery. These studies are recruiting participants who receive mental health services within the VA Maryland Healthcare System. Below are descriptions of them, with phone numbers to call if you or someone you know receives mental health services within the VA Maryland Healthcare System and would like to learn more.

We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to complete assessments of symptoms and functioning. The study would require 2 to 4 hours of your time. If you qualify, you would be paid $45 for your participation.

Interested in participating?
Please call Sera Havrilla at 410-637-1425.

Flyer Aim 4
Interested in Research?
We are looking for Veterans, aged 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to complete assessments of symptoms and functioning.

The study would require up to 4 hours of your time. If you qualify, you would be paid $45 for your participation.

VISN 5 Mental Illness Research Education and Clinical Center
Interested in participating? Grab a number below and call for more details!

Small Flyers (4/page)
Aim 3
Interested in getting in shape?
We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to participate in a research study involving exercise.
If you qualify, you would receive free access to personalized fitness training at the VA!
Questions? Need more information? Interested in participating?
Please call Kinnera Atluri at 443-421-8958.
VISN 5 Mental Illness Research Education and Clinical Center

Aim 4
Interested in Research?
We are looking for Veterans, ages 50 and older, who have been diagnosed with a serious mental illness (for example, depression with psychotic features, schizophrenia, or bipolar disorder) to complete assessments of symptoms and functioning. The study would require up to 4 hours of your time. If you qualify, you would be paid $45 for your participation.
VISN 5 Mental Illness Research Education and Clinical Center
Interested in participating?
Please call Sera Havrilla for more details!
410-637-1425

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Aim 3 quarter flyer 12.11.2020(0.03)	1/29/2020 8:25 AM	12/15/2020 1:59 PM
Handout Aim 3 12.10.2020(0.05)	11/4/2016 10:29 AM	12/15/2020 1:59 PM
Flyer Aim 3 12.10.2020(0.06)	11/4/2016 10:29 AM	12/15/2020 1:58 PM
Aim 4 quarter flyers(0.01)	1/29/2020 8:25 AM	1/29/2020 8:25 AM
Flyer Aim 4(0.03)	9/12/2018 3:24 PM	9/13/2018 11:59 AM
Handout_Aim2.pub(0.01)	10/24/2016 4:33 PM	10/24/2016 4:33 PM
Flyer_Aim2.pub(0.01)	10/24/2016 4:33 PM	10/24/2016 4:33 PM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

HP-00072447 Research Related Risk_V2

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

There are no major or minor risks to participating for participants in Aim 1.

The following are risks for participants in Aims 2 and 3:

(1) Some participants may feel embarrassed when they have to answer questions that they may feel are personal (small likelihood, low degree of seriousness). To minimize this risk, participants are told before each assessment the nature of the questions being asked and are told to answer honestly but to feel free to not answer questions that make them feel uncomfortable. Study interviewers are trained to talk about personal material with patients and to engage in discussions in a supportive and empathic and nonjudgmental way.

(2) Participant may feel bored or tired due to the length of time required to complete the interviews/assessments (moderate likelihood, low degree of seriousness). To address this risk, participants will be given the option of scheduling the assessments over multiple visits. In cases in which a participant is tired or bored during an assessment/interview, he/she will be offered breaks or allowed to end the assessment and finish the remainder on another day.

(3) Distress during assessments and interviews (small likelihood, low degree of seriousness). Before consent and before and during data collection, participants are informed that they are free to decline to answer any question(s) or to discontinue at any time. If participants feel uncomfortable or fatigued, or seem so to the research staff, they are encouraged to take a break and continue again later, or to stop the interview. In our research with people with serious mental illnesses over the past several years, few research participants have experienced distress from participating in assessments and interviews. Nonetheless, research staff have been trained to stop surveys/interviews if a participant becomes distressed and will have the resources needed to assist him/her in obtaining the level of support or assistance they require, including crisis intervention if needed.

(4) Distress During Groups (small likelihood, low degree of seriousness). Participants may feel self-conscious sharing their beliefs/thoughts while in research groups. We will minimize this risk by reminding participants that they can choose to NOT answer questions if they feel uncomfortable. We will also remind all participants that what is said in group should remain confidential and not be shared with anyone outside of group.

(5) Potential loss of confidentiality (small likelihood, moderate degree of seriousness). All project staff are thoroughly trained in issues relating to maintaining confidentiality of research data. There is a slight risk of a confidentiality breach related to data collected for research purposes from participant assessments and medical records. Study participants will be informed that information obtained through research interviews is confidential; potential risks to data security and the measures we take to protect it will be reviewed with them during the informed consent process. Numerous steps will be taken to ensure research interview data confidentiality and security. To protect confidentiality, hard copies of survey/interview data and data obtained from participants' medical records are identified only by an anonymous code number assigned to each research participant and are kept in a locked file cabinet behind a locked office door at the VA Maryland Health Care System. Only designated research staff members have access to the password protected file that links participants' identities to their codes. This file is located on a secure server located in the VA Maryland Health Care System. Hardcopies of consent forms which contain participants' names are kept separately in a locked cabinet in a locked office that is located in the VA Maryland Health Care System. Electronic data are kept on a password protected computer server and/or saved in a restricted access folder to prevent any unauthorized access to participant information. All electronic research data with identifiers will be stored at our research offices at the VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD) behind the VA firewall or the Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201). In the event of any incidents, unauthorized access of sensitive data or storage devices or noncompliance with security controls, the PI or another member of the research staff will immediately contact the VAMHCS Information Security Officer Privacy Officer and the VAMHCS Research Compliance Officer and the University of Maryland IRB.

(6) Some participants may feel uncomfortable with being audio or video recorded (small likelihood, low degree of seriousness). There is also a slight risk of a breach of confidentiality regarding the identities of the participant on the recording. To minimize this risk, research staff will label all recordings with an anonymous code. Access to the file that links participant names to their project ID number will be stored behind the VA firewall at research offices at the VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD).

(7) Assessments of mobility function (MPPT and 6MWD) involve a variety of timed walks, tests of balance, stair climbing, and getting up from a chair. There is a slight risk that participants will fall (small likelihood, moderate degree of seriousness). There is a risk that participants will experience leg claudication pain, chest pain, or become short of breath or dizzy during these tests (moderate likelihood, low degree of seriousness). Participants will be asked to inform the research staff of any symptoms they experience during these assessments, and will be allowed to take breaks or stop assessment procedures as needed. Trained study personnel will be administering these tests. Study staff trained in CPR will administer these tests. Assessments will take place in a facility where emergency medications and resuscitation equipment are available.

(8) Aerobic Exercise Training: Aerobic exercise is associated with the risk of cardiovascular complications such as chest pain, heart attack, or sudden death and complications related to stress and strains of muscles, twisted ankles, or falls. This risk is increased in patients who have heart disease, poor circulation to the legs, or stroke. The American Heart Association consensus statement on exercise standards estimates that the acute risk of sudden cardiac arrest during exercise training in patients with known cardiac disease is approximately 1 event per 60,000 hrs of aerobic exercise. There is also the risk of hypoglycemia in subjects with T2DM; we will minimize this risk with careful monitoring before and after exercise as noted in the procedures. Exercise sessions will take place at a VAMHCS exercise facility and will be supervised by exercise physiologists who are certified in exercise training and CPR. To minimize risk to patients, heart rate will be assessed before, during and after each session and blood pressure before and after each session. If blood pressure or heart rate go too high or subjects develop an irregular heart rate, chest pain or leg cramps, the training is stopped immediately. A clinical provider is on call and can be reached by phone for consult in case of any problems. An AED is available on-site and, should there be any unanticipated medical emergencies, staff can initiate emergency care by calling 911. We believe that it is highly unlikely that a subject will develop a medical emergency that would require the 911 system to be activated as in more than 25 years of training more than 1000 research subjects we have only had 1 subject who had a heart attack during aerobic training. For subjects with peripheral neuropathy, there may be a risk of developing sores or ulcers on the feet. This risk is reduced by wearing proper footwear during exercise.

(9) Participants may be asked to provide blood samples as part of the screening process in order to determine eligibility. The risks for blood sampling include discomfort, bruising, swelling, fainting, and possible infection at the site of sampling. This is minimized by having skilled medical personnel perform the sampling. Participants will be told they can contact the research staff or the PI if they experience discomfort or complications at the blood draw site.

(10) Participants may experience discomfort when wearing pedometers to measure step-counts. Participants will be trained in the appropriate use of these devices and will be provided with the telephone contact information of the research staff should any questions arise. Participants will be told that if they feel discomfort, they may remove the pedometer if they choose.

(11) See "UMB COVID Risk Statement" in Additional Documents.

Aim 4: Risks 1, 2, 3, 5, 6, 7, and 11 listed above are also potential risks or discomforts for this aim as it includes an assessment battery which may be audio/video recorded, and tests of mobility, physical function, and physical activity.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
Aim 1: Participants will have the opportunity to influence the development of a new intervention.

Aims 2 and 3: There may be no direct benefits for those individuals who choose to participate. However, participants may learn strategies to increase their daily physical activity and exercise.

Aim 4: There may be no direct benefit, however, their participation could help investigators better understand this population of veterans.

2 * Describe the importance of the knowledge expected to result from the study:
This research will contribute to our understanding of how to promote physical activity in older adults with psychotic disorders.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The major risks to participants are boredom, embarrassment, potential loss of confidentiality, and physical discomfort and distress during mobility function assessments and exercise training. These risks are outweighed by the potential benefits of better understanding of how to promote physical activity in older adults with psychotic disorders. This understanding could lead to targeted interventions to prevent functional decline and promote functional independence in this population.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
The study is voluntary. The alternative is to ask one's medical or mental health provider for referrals to VA programs focused on increasing exercise and physical activity (e.g., the MOVE! program).

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

HP-00072447

Withdrawal of Participants_V2

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:

Participants will be withdrawn without their agreement under the following circumstances:

1) They experience severe distress during the study.
2) They fail to follow instructions from research staff.
3) If the PI decides that the study is no longer in the best interest of the participant. This includes if something changes in the health of the participant and participating in the study and/or participating in supervised fitness training would be contraindicated (i.e. identification of a new health condition, worsening of a current health condition, etc.)

These circumstances have been outlined in the informed consent form.

2 * Describe procedures for orderly termination:

We will close the study after the last participant interaction occurs and all data has been collected.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:

If a participant decide to withdraw from the research, all data already collected will remain in the database, but no new data will be collected from the participant. This information is included in the VA mandated consent form.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

HP-00072447

Privacy of Participants_V2

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***

Research staff are thoroughly trained to protect the privacy of research participants. We meet with participants in private rooms with closed doors at the VAMHCS and/or remotely if needed.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:

Potential VA participants will receive research information in a private room with the door closed within the VA Maryland Health Care System (VAMHCS). For remote appointments, research staff will work from a private space and will ensure that the participant is also in a private space prior to beginning any research procedures.

3 * Describe potential environmental stressors that may be associated with the research:

There are no environmental stressors associated with this research.

4 * Will this study have a site based in the European Union?

○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?

○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

HP-00072447 Confidentiality of Data_V2

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

All data will be assigned a participant number. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall. Access to the link file will be limited to only study staff listed on this protocol.

All data, including the investigator's research records and any participant identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). After the study project is complete, all data, including hard copies and electronic files will be kept at the VA for final storage.

Documents for this study include:

1. Documents with identifiable information: Informed Consent Forms (ICF's), HIPAA Authorization forms, Evaluation to sign ICF, Exercise prescriptions, exercise test reports
2. Coded data: (2a) hard copies of interviews, surveys, and assessments and (2b) coded electronic data
3. CDs/DVDs/Electronic audio recordings

(1) Documents with identifiable information

ICF's, HIPAA Authorization Forms and the Evaluation to Sign Consent contain participants' names but not their project ID number. When these documents are collected at the VA they are kept in a separate locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201). If the consent visit is completed remotely, all consent-related documents will be stored in our study restricted access folder which is limited to project staff only.

Exercise prescriptions and exercise test reports contain participants' names but not their project ID number. Exercise prescriptions are kept in a separate locked cabinet in a locked office at the VA site where the participant completes their exercise training sessions (VA Annex, 209 W. Fayette Street, Baltimore, MD 21201 or 3900 Loch Raven Blvd, Baltimore, MD 21218). Exercise testing and reports to determine study eligibility will be completed and temporarily stored at the GRECC offices in the Baltimore VA Medical Center in locked cabinets in a locked office (10 N. Greene St, 4th floor, Baltimore, MD 21201). Once the reports are complete and an eligibility determination is made, the reports will be transported by hand in a locked bag to the MIRECC offices (VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201) and stored in a locked cabinet in a locked office.

2a) Coded data, hard copies

All hard copies of coded research assessments will be stored in a locked cabinet in a locked office in the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201), or will be transported by hand in a locked bag and stored in a locked cabinet in a locked office in the University of Maryland, Division of Psychiatric Services Research for data entry. Once data is entered, it will be returned to VA for final storage. Data collected remotely, if meeting face-to-face is not possible, will be securely stored in a locked HIPAA bag and transported to the VA as soon as possible. Access to hard copies of coded research assessments will be limited to only study staff listed on this protocol.

2b) Coded electronic data

The CTRIC team will create a REDCap database to the PIs specifications. Paper copies of coded research data (assessments) will be entered into, stored and managed by a VA REDCap database. REDCap is a free, secure Web application installed on the VA intranet that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable VA users to quickly develop surveys and databases from conception to production on the web without additional software requirements. This tool helps VA researchers enter, store, and manage their project data in a systematic manner. This service is provided through the VA Information Resource Center (VIReC) that develops resources for and provides guidance to VA researchers using data. The VIReC's staff, scientists, and advisors include database and informatics experts, research methodologists, and experts for various database content areas. The database is configured to use FIPS 140-2 encryption available in the underlying infrastructure to protect sensitive data at rest. In addition, the information system and its dependencies have gone through the VA Assessment and Authorization (A&A) process to evaluate any associated risks and was granted an Authorization to Operate (ATO) as indicated. Primary data are stored at the secure VA Austin Information Technology Center (AITC), located in Austin, Texas on a VINCI Server. Data are backed up nightly and REDCap provides detailed audit trails and specific controls over user rights. Users must have a VA account to log in to REDCap.

3) CDs/DVDs/electronic audio/video recordings

Audio/Video Recordings may be viewed for supervision purposes by the PI and the other members of the research staff that administer these interviews. All CD's, DVD's, and recorders containing audio/video recordings will be collected at the VA and/or remotely if meeting face-to-face is not possible. Data collected at the VA will be stored in a locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201). Data collected remotely will be stored securely in a locked HIPAA bag and transported to the VA as soon as possible. Electronic audio files will be stored securely behind the VA Firewall in the Baltimore MIRECC Restricted Share Drive with access available to study staff only. All audio/video recordings will be identified by codes only, and will not contain participants' names. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall.

3 * How will such data be secured?

All data will be assigned a participant number. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall. Access to the link file will be limited to only study staff listed on this protocol.

All data, including the investigator's research records and any participant identifiers will be retained in accordance with the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). After the study project is complete, all data, including hard copies and electronic files will be kept at the VA for final storage.

(1) Documents with identifiable information

Documents with identifiable information will not have participant ID numbers on them. They will be kept in a separate locked cabinet in locked offices at the VA.

(2a) Coded data, hard copies

All hard copies of coded research assessments will be stored in a locked cabinet in a locked office in the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201), or will be transported by hand in a locked bag and stored in a locked cabinet in a locked office in the University of Maryland, Division of Psychiatric Services Research for data entry. Once data is entered, it will be returned to the VA for final storage. Data collected remotely, if meeting face-to-face is not

possible, will be securely stored in a locked HIPAA bag and transported to the VA as soon as possible. Access to hard copies of coded research assessments will be limited to only study staff listed on this protocol.

2b) Coded electronic data

Paper copies of coded research data (assessments) will be entered into, stored and managed by a VA REDCap database. REDCap is a free, secure web application installed on the VA intranet that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable VA users to quickly develop surveys and databases from conception to production on the web without additional software requirements. This tool helps VA researchers enter, store, and manage their project data in a systematic manner. This service is provided through the VA Information Resource Center (VIReC) that develops resources for and provides guidance to VA researchers using data. The VIReC's staff, scientists, and advisors include database and informatics experts, research methodologists, and experts for various database content areas. The database is configured to use FIPS 140-2 encryption available in the underlying infrastructure to protect sensitive data at rest. In addition, the information system and its dependencies have gone through the VA Assessment and Authorization (A&A) process to evaluate any associated risks and was granted an Authorization to Operate (ATO) as indicated. Primary data are stored at the secure VA Austin Information Technology Center (AITC), located in Austin, Texas on a VINCI Server. Data are backed up nightly and REDCap provides detailed audit trails and specific controls over user rights. Users must have a VA account to log in to REDCap.

3) CDs/DVDs/electronic audio recordings

All CD's and DVD's of audio/video recordings will be collected at the VA and/or remotely if needed. Data collected at the VA will be stored in a locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, Baltimore, MD 21201). Data collected remotely will be stored securely in a locked HIPAA bag and transported to the VA as soon as possible. Electronic audio files will be stored securely behind the VA Firewall. All audio/video recordings will be identified by codes only, and will not contain participants' names. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall.

4 * Who will have access to research data?

The PI, co-investigators, and authorized research study staff listed on this protocol will have access to the research data. Access to data will be terminated for study staff that are no longer part of the research study.

Audio recordings of interviews collected for this study will be sent securely to a VA-approved transcription agency. These audio recordings will not contain any identifiable information.

5 * Will study data or test results be recorded in the participant's medical records?

● **Yes** ○ No

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research and VA research cannot be deleted)***

● **Yes** ○ No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

Data for this study will be destroyed in accordance with the VA Records Control Schedule.

7 Do you plan to obtain a Certificate of Confidentiality?

○ Yes ● **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

Please note that this project will keep within the following VA guidelines: a) full social security numbers of veterans will not be solicited, b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol, c) initial contact with veterans must be made in person or by letter prior to telephone contact, and d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

In the event of any incidents, unauthorized access of sensitive data or storage devices or noncompliance with security controls, the PI or another member of the research staff will immediately contact the VAMHCS Information Security Officer, VAMHCS Privacy Officer and the VAMHCS Research Compliance Officer and the University of Maryland IRB.

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

HP-00072447

Monitoring Plan Selection_V2

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ● **Data Safety Monitoring by a Committee**
- ○ Data Safety Monitoring by an Individual
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

HP-00072447

Monitoring Plan - Committee_V2

Monitoring Plan - Committee

You indicated that the monitoring will be done by a Committee.

1 * Will the Committee be Internal or External?

- (●) **Internal DSMB**
- ( ) External DSMB

2 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [x] **Patient Charts/Clinical Summaries**
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [x] **Procedure Reports**
- [ ] Raw Data
- [ ] Outcomes (Primary, Secondary)
- [ ] Preliminary Analyses
- [x] **Other**

2.1 If Other, specify:
QA audit reports, SOP and consent forms when indicated

3 * What will be the frequency of the review?

- ( ) Annually
- (●) **Bi-Annually**
- ( ) Other

3.1 If Other, specify:

4 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [x] **Other**

4.1 If Other, specify:
VA R&D and compliance office; GRECC internal and external advisory committees

ID: VIEW4E1B025761800
Name: v2_Monitoring Plan - Committee

Monitoring Plan - Internal DSMB

You indicated that the monitoring committee will be an internal DSMB.

1 * List Internal DSMB Members:

Name
View See list of members in the ISMB Plan attached in Additional Documents

2 * Confirm that no financial or other conflicts of interest exists for the above individuals.

● **Yes** ○ No

3 * Will there be an interim efficacy analysis?

○ Yes ● **No**

3.1 If Yes, when?

4 * Briefly describe the DSM review process itself. Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?

The ISMB meets twice a year. This will be an open review, but investigators are not allowed to vote on their own protocols. No PHI will be revealed when SAEs are reviewed. Aggregate data will be presented.

5 * What are the criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study?

Failure to follow good clinical practice, investigator noncompliance, failure to meet enrollment goals may be grounds for suspension or termination of a study.

ID: VIEW4E1B0261D9400
Name: v2_Monitoring Plan - Internal DSMB

HP-00072447

Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☐ Investigational or Study Device
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

● **Yes** ◯ No

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

The VA mandated consent form indicates the following for participants:

If you are injured as a result of taking part in this study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

1.2.2

Name	Created	Modified Date
compensation for research-related injury language.docx(0.01)	10/28/2016 10:20 AM	10/28/2016 10:20 AM

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00072447

Payment Detail_V2

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [ ] Travel
- [ ] Parking
- [ ] Meals
- [ ] Lodging
- [x] **Time and effort**
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***
up to 120/80/200/45

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
Aim 1:
Veterans Advisory Panel members will receive $20 for each meeting they attend, up to $120.

Aim 2:
Participants will receive $40 upon completion of a screening visit.
Participants will receive $40 upon completion of a qualitative interview, following 12 weeks of the PEER intervention.
Total: $80

Aim 3:
Participants will receive $50 upon completion of consent, screening, and baseline assessment procedures.
Participants will receive $50 upon completion of time point 2 assessments (~12 weeks after randomization)
Participants will receive $50 upon completion of time point 3 assessments (~24 weeks after randomization)
Participants will receive $50 upon completion of a one-time qualitative interview after time point 3.
Total: $200

If any of the above assessments need to be completed via phone (instead of face-to-face) they will be mailed payment to ensure prompt receipt of funds.

Aim 4:
Participants will receive $45 upon completion of the assessment.

4 * Method(s) of payment/reimbursement to be Used:

- [ ] Cash
- [x] **Check**
- [ ] Money Order
- [x] **Gift Certificate/Gift Card**
- [x] **Other**

4.1 If Other, specify:
Veteran participants will either be given a gift card, check, VA voucher, or an equivalent payment method. VA payment vouchers can be taken to the VA agent cashier and redeemed for cash.

If a participant expresses to study staff they he or she is having difficulty attending study appointments due to lack of transportation then a bus token, or equivalent travel voucher, will be offered to the participant if available.

In Aims 2 and 3, participants that reach their personal fitness goals will have the opportunity to win a prize valued at $10 or less during PEER group sessions.

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HP-00072447 HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● **Yes** ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [x] **Dates**
- [ ] Ages over age 89
- [x] **Telephone numbers**
- [ ] Fax numbers
- [ ] Email addresses
- [x] **Social Security numbers**
- [ ] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [x] **Biometric identifiers, including fingerprints and voiceprints**
- [x] **Full-face photographic images and any comparable images**
- [x] **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification**
- [ ] None

2 * Why is the PHI necessary for this research?

If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).

This PHI is necessary in order to identify and screen for study eligibility criteria. We collect names, addresses and phone numbers to be able to contact participants for all aspects of their participation in the study, and to be able to send them a letter if needed. Date of birth is collected in order to verify age and identify them in our study database. The VA requires that the last four digits of SSN of the participant be included on all consent and HIPAA forms. This is a VA requirement, and not a procedure required for this study specifically. Each participant in the study is assigned an ID number that will be linked to their name, so identifying number/code has been checked for this purpose.

Voiceprints and images are collected through our audio and video recordings, and these are used to collect data, and for training and supervision of staff.

3 * What is the source(s) of the PHI?

We collect this information from participant's medical records or from the participant during the course of their participation in the study.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).

PHI collected for this study will only be used for the purposes described in this protocol. This information will not be reused or disclosed to any other entity outside this study.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

HP-00072447

Waiver - Alteration of Authorization_V2

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
We request a partial waiver of HIPAA authorization for this study for recruitment purposes only. This waiver of HIPAA authorization for recruitment purposes is justified because the use of information includes no more than minimal risk to the confidentiality of the participants' information. Information collected through this waiver will only be used by study staff listed in this protocol and will not be shared with anyone outside of the project.

In addition, a temporary waiver of documentation of written HIPAA consent is being requested in order to allow consent visits to happen remotely.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
The information requested for use in our waiver of HIPAA Authorization will be protected by study staff from improper use and disclosure. This information will not be reused or disclosed to any other person or entity outside of this research project. This information will be stored in a secure and locked cabinet and/or on a password protected computer kept in a locked office at the VAMHCS. Only study staff will have access to this information.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
After the sample is recruited all identifiers from potential participants who did not agree to participate or who were found to be ineligible will be destroyed/shredded within approximately 6 months of closing the study.

4 * Why could the research not practicably be done without access to and use of this PHI?
This research could not practicably be conducted without access to and use of this PHI. Access to this PHI allows research staff to screen medical records and determine eligibility prior to approaching Veterans about the study. Without access to this PHI we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. A burden would also be placed on study staff whose time would be wasted by approaching non-eligible Veterans.

5 * Why could the research not practicably be done without the waiver or alteration?
This waiver allows us to screen medical records for study eligibility criteria and then only approach those Veterans who appear eligible based on this screening. Without this waiver we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. A burden would also be placed on study staff whose time would be wasted by approaching non-eligible Veterans.

Subsequent to the VA Office of Research & Development administrative hold on in-person research due to COVID-19, VA ORD announced July 31, 2020 that they will allow VA researchers to present safety plans and request permission to resume in-person research. Whenever possible, this study is modifying activities which must be conducted in person including signing hardcopies of Informed Consent Forms and HIPAA Consents. In order to avoid undue risk to our participants and research staff we are requesting a Waiver of Documentation of Consent and HIPAA so the appointment can be completed remotely.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
● **Yes** ○ No

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.
This is a VA study, employing VA staff. The VA study staff will have access to PHI.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [x] **Request to Waive Consent/Parental Permission (Consent is not being obtained)**
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [x] **Request to Waive Documentation of Consent (Verbal/Oral Consent)**
- [x] **Written Consent Form**
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:

For Aim 1, oral consent will be obtained from expert panelists. An informational sheet outlining the basic elements of consent will be provided to all panelists prior to their participation.

For Aims 2 and 4 written informed consent will be secured from all participants. During Aim 3, which is ongoing, if meeting face-to-face is not feasible due to COVID-19 precautions we will obtain verbal consent and therefore request a waiver of written documentation of consent. Research staff will mail potential participants a copy of the informed consent documents and then meet with the potential participants by phone or VA Virtual Care Manager (telehealth) once they have received it. Veteran participants will also receive a Health Insurance Portability and Accountability Act Authorization to Obtain, Use and Disclose Protected Health Information for Research (HIPPA) that will also be summarized for them. In addition, the UMB COVID Risk Statement (see Additional Documents) will be mailed to participants and will also be summarized during the remote informed consent appointment. Staff will ask participants if they have any questions once the document has been read and verbally confirm that the Veteran participant consents. Once COVID-19 precautions are no longer necessary, the research study can return to the previously approved consent protocol to complete this process face-to-face.

Our research staff are carefully trained on obtaining consent from participants with serious mental illness and supervised by senior staff members. In consultation with the study PI as needed, research staff will screen for clinical stability using chart review and/or communication with potential participants' mental health providers, before approaching a potential participant. The study interviewer will then provide an overview of the project, and invite him/her to participate. Potential participants are provided an informed consent form. Staff members are trained to recognize symptoms of severe mental illness and cognitive impairment that could undermine a participant's ability to provide informed consent. The consent form is summarized to all participants in detail, and participants are given time to ask any questions they may have and to discuss the form and its contents with the research staff.

After the consent form has been reviewed in detail with the participant and all questions have been answered, the staff confirms that the participant is still interested in participating by soliciting a verbal response. Those who express willingness to provide consent must complete a brief questionnaire to assess competency and understanding of the consent form (see evaluation to sign consent questions in additional documents). If the participant is unable to answer the questions correctly, staff re-reviews the aspects of the study that the participant did not understand. The staff member asks the questions a second time. If the participant cannot answer all questions correctly, he/she will not be enrolled in the study.

Per IRB regulations, for in-person consent appointments, a copy of the signed consent form is given to the participant, and the original is kept in the researcher's offices at the VA Maryland Health Care System. Participants will also receive a Health Insurance Portability and Accountability Act Authorization to Obtain, Use and Disclose Protected Health Information for Research (HIPPA) that will also be summarized for them. Staff will ask participants if they have any questions once the document has been reviewed, and then participants will sign the authorization. A copy of this signed form will be given to the participant, and one will be kept in the researcher's offices at the VA Maryland Health Care System.

In keeping with the requirements put forth in the Department of Veterans Affairs: a) full social security numbers of veterans will not be solicited; b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol; c) initial contact with veterans must be made in person or by letter prior to telephone contact; d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

For VA facilitator participants:
Facilitators will have the option of completing the interview in person or over the telephone, depending on their location. In both instances, however, all study materials, including the study informed consent form, the Notice of Privacy Practices, and the NOPP signature page, will be emailed to providers ahead of time for their review. Prior to the actual interview, the study team member will review the purpose of the study, procedures, risks, and benefits. Facilitators will be given the chance to ask questions at that time. If the provider agrees to participate, they will go on to sign all enrollment documents. If the interview is being conducted via telephone, the provider will sign all paperwork and return it to study staff either via email or fax. If the interview is being conducted in person, the research staff will retain the signed paperwork for research files. The Facilitator Informed Consent Form and NOPP paperwork will be returned to study staff prior to the initiation of the interview. Facilitators will be given copies of all paperwork to keep for their own records.

Oral consent will be obtained for the Aim 2 and 3 participants who complete the follow-up qualitative interview. Information outlining the basic elements of consent will be provided verbally to ensure their understanding prior to their decision regarding participation. All of these participants have previously given their written permission for us to follow up with them after they finish study participation in order to follow up with them about their experience.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

(●) **Yes** ( ) No

4 * Describe who will obtain Informed Consent:
The research staff listed on this protocol.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
Informed consent will take place in a private office or room with a closed door or via phone/ VA Virtual Care Manager telehealth platform.

7 * Describe the provisions for assessing participant understanding:
Participants must correctly answer a set of questions regarding the study. If they do not answer all of the questions correctly after 2 attempts, they will not be eligible to participate.

8 * Describe the consideration for ongoing consent:
Staff will review the procedures of the protocol, potential risks and benefits, right to withdraw and how confidentiality of research data will be maintained with the participant before each interview. If they are not able to provide continued consent, they will be removed from the study.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Waiver of Documentation of Consent

You indicated that a waiver of documentation of consent (verbal/oral consent) is requested.

1 * Indicate why a waiver of documentation of consent is being requested for the study:

- ○ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.
- ● **The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.**

2 * Provide a justification/explanation for the choice above:

We are requesting a waiver of documentation of consent for Aim 1, in which participants are expert panelists providing feedback on drafts of an intervention.

We are also requesting a waiver of documentation of consent for Aim 2 and 3 participants who participate in the follow up qualitative interview. This presents no risk to subjects and involves no procedures for which written consent is required outside of the research context.

In addition, a temporary waiver of documentation of written consent is being requested in light of COVID-19 for Aim 3 participants until it is deemed safe to resume meeting with participants in person. This waiver will prevent unnecessary face-to-face visits and limit undue risk to our veteran participants and research staff.

ID: VIEW4E1C6EF6F5000
Name: v2_Waiver of Documentation of Consent

Waiver or Alteration Consent Process

You indicated that a waiver/alteration of consent is requested.

1 * Explain why the research involves no more than minimal risks to the subjects:
First we request a waiver of informed consent for recruitment purposes only, as required by the VA for studies that also obtain a waiver of HIPAA authorization for recruitment purposes. We will view information to determine eligibility but no research procedures will be conducted until such time that the participant agrees to take part in the study and signs the informed consent document. The recruitment process involves no more than minimal risk to the individual.

Second, we request a temporary waiver of documentation of written consent to prevent undue risk to participants and staff in light of COVID-19. While the research study is no more than minimal risk, traveling to and participating in additional in-person procedures, which can be easily completed remotely, should be avoided during this time.

2 * Explain why a waiver or alteration of the consent process would not adversely affect the rights and welfare of the subjects:
The first waiver request is for recruitment purposes only as required by the VA. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or complete the remote informed consent process or they can decline participation.

In regards to the temporary Waiver of Documentation of Consent, study participants will still receive a copy of the consent documents, complete the Informed Consent Process, and verbally consent to participate instead of signing the ICF document.

3 * Informed consent is always required unless there is reason to grant a waiver or alteration of the consent process. Explain why you cannot carry out the research unless you are granted a waiver or alteration of the consent process:
The first waiver request is for recruitment purposes only as required by the VA. If it is determined that the individual would be eligible to take part in the study, they will be approached and given the opportunity to agree and sign the informed consent document or they can decline participation.

In regards to the temporary Waiver of Documentation of Consent, since we are recruiting veteran participants age 50 and up who are at greater risk for the adverse effects of the COVID-19 virus, we believe that asking them to come in for in-person visits which can easily be completed remotely is an unnecessary risk at this time. We believe that the safer approach is to modify to remote visits when possible in order to protect their safety and the safety of our research staff. Therefore we request a temporary waiver of documentation of consent as this study continues to be minimal risk but unnecessary travel and presence in VA facilities for in-person consent procedures should be avoided right now when possible.

4 If the research involves using identifiable private information or identifiable biospecimens, please explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

5 In some cases there will be additional pertinent information during the study that should be given to the participating subjects. For those subjects who have not been given informed consent because there is a waiver or alteration of the consent process, explain how the subjects will receive this additional important information. If applicable, please explain why a subject would not receive additional pertinent information.
N/A. Individuals who would be eligible to take part in the study will be given the opportunity to agree and sign the informed consent document or complete the remote informed consent process or to decline participation.

6 If you are requesting an alteration of the consent process please explain why this request is necessary for the conduct of the research study. Please identify specifically what is being altered or changed in the consent process.
N/A

ID: VIEW4E1C73B344800
Name: v2_Waiver/Alteration of Consent Process

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
PEER Aim 3 Consent 02.22.2021 Redline.docx(0.12)	5/1/2019 3:39 PM	2/22/2021 2:18 PM
PEER Aim 3 Consent 02.22.2021 Clean.docx(0.22)	3/9/2018 11:06 AM	2/22/2021 2:18 PM
PEER Consent for Facilitators 10.22.18(0.04)	9/14/2018 3:45 PM	10/22/2018 4:38 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
PEER Aim 4 Consent 11.6.2019 Redline Version(0.02)	2/8/2019 9:53 AM	11/6/2019 12:49 PM
PEER Aim 4 Consent 11.6.2019(0.07)	9/14/2018 3:45 PM	11/6/2019 12:49 PM
Aim 3 ICF Addendum(0.02)	5/1/2019 4:47 PM	5/2/2019 4:14 PM
Aim 2 ICF redline version 4.26.2018(0.01)	4/26/2018 8:09 AM	4/26/2018 8:09 AM
Aim 2 ICF 4.26.2018(0.03)	3/9/2018 11:06 AM	4/26/2018 8:08 AM

2 Upload any HIPAA authorization forms here:

PEER_HIPAA_Aim 4(0.02)	9/14/2018 3:46 PM	9/18/2018 7:56 AM
PEER_HIPAA_Aim3.pdf(0.03)	11/4/2016 12:24 PM	4/28/2017 10:38 AM
PEER_HIPAA_Aim2.pdf(0.03)	11/4/2016 12:24 PM	4/28/2017 10:38 AM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates:
http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Psychiatry

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ● **Yes** ○ No

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ● **Yes** ○ No

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ● **Yes** ○ No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

VA-Specific Criteria

1 * What is the relevance of this research to the mission of VA and the Veteran population that it serves*?
Veterans with psychotic disorders are aging into older adulthood in unprecedented numbers. These Veterans have complex care needs across psychological, social, environmental, and physical domains. Innovative interventions to improve the health and functioning of this population are sorely needed.

2 * Describe who will be enrolled in this study:

- ○ Non-veterans will be enrolled in this study
- ○ Only veterans will be enrolled in this study
- ● **Veterans and Non-veterans will be enrolled in this study**

2.1 * If non-veterans will be enrolled in this study, provide a description of non-veterans who will be enrolled (For example: community members, family members/caretakers of Veterans, clinicians/caregivers to Veterans, etc.):
For Aim 1 only, expert panelists may include non-Veterans. Non-Veteran expert panelists are individuals with clinical and/or research expertise in a topic area relevant to the intervention being developed.

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:
Non-Veteran expert panelists are individuals with clinical and/or research expertise in a topic area relevant to the intervention being developed. They will make unique and substantive contributions to improve the quality of the intervention, which may in the long-term improve the care of older Veterans with serious mental illness.

2.3 * If this is a VA-funded study, was the use of non-veterans discussed within your merit award proposal?

- ● **Yes**
- ○ No
- ○ N/A

*
http://www.va.gov/about_va/mission.asp

VA Mission Statement
To fulfill President Lincoln's promise “To care for him who shall have borne the battle, and for his widow, and his orphan” by serving and honoring the men and women who are America’s Veterans.

VA Core Values
VA’s five core values underscore the obligations inherent in VA’s mission: Integrity, Commitment, Advocacy, Respect, and Excellence. The core values define “who we are,” our culture, and how we care for Veterans and eligible beneficiaries. Our values are more than just words – they affect outcomes in our daily interactions with Veterans and eligible beneficiaries and with each other. Taking the first letter of each word—Integrity, Commitment, Advocacy, Respect, Excellence—creates a powerful acronym, “I CARE,” that reminds each VA employee of the importance of their role in this Department. These core values come together as five promises we make as individuals and as an organization to those we serve.
Integrity: Act with high moral principle. Adhere to the highest professional standards. Maintain the trust and confidence of all with whom I engage.
Commitment: Work diligently to serve Veterans and other beneficiaries. Be driven by an earnest belief in VA’s mission. Fulfill my individual responsibilities and organizational responsibilities.
Advocacy: Be truly Veteran-centric by identifying, fully considering, and appropriately advancing the interests of Veterans and other beneficiaries.
Respect: Treat all those I serve and with whom I work with dignity and respect. Show respect to earn it.
Excellence: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.

**
a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. The investigator must justify including non-Veterans and the IRB must review the justification and provide specific approval for recruitment of non-Veterans.
b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans’ family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.
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e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

[VHA Handbook 1200.05 §24]

HP-00072447

VA Prohibited Research_V2

VA Prohibited Research

1 * Is the research planned emergency research in subjects from whom consent can not be prospectively obtained?
◯ Yes ● **No**

2 * Does the study involve children **AND** is greater than minimal risk?
◯ Yes ● **No**

3 * Will recruitment phone calls involve asking veterans for their Social Security numbers?
◯ Yes ● **No**

ID: VIEW4E1C8AF03A400
Name: v2_VA Prohibited Research

HP-00072447 Additional VA_V2

Additional VA

1 * For data that is combined, which site is the "Data Coordinating Center"?
Data is not combined

2 If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored.

3 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data collected? (This answer may overlap with Research Related Procedures. If so, please refer to that section.)

4 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data received and combined with the UM data?

5 If the UM is the Coordinating Center holding the "combined data", will you only use the combined data set while not on VA time or will you obtain approval from VA ORD/Regional Counsel to do this as an "off-site" VA Research activity.

ID: VIEW8D5931EAC5B1E6E
Name: v2_Additional VA

HP-00072447 VA Review Required_V2

VA Maryland Health Care System Review Required

1

Note: Based on the answers provided in your submission, this protocol qualifies as a VA study. Therefore, VAMHCS Research &Development (R&D) Committee approval (in addition to IRB approval) is required prior to engaging in any research activities. **Importantly, you must submit the protocol to the VAMHCS Research Service within 60 days of IRB approval.**

**Details related to the VA submission and approval processes are best obtained by calling or visiting the Baltimore VA Research Office (Fred Ivey @ 410-605-7000 x6582). Despite not being able to submit at VA until after IRB approval is obtained, we strongly encourage immediate consultation with the VA R&D service, allowing time for early familiarization with VA requirements and VA Service clearance for your proposed work.

VA Research Service **Forms** can be accessed using the following link:

https://www.maryland.va.gov/research/human/human_subject_forms.asp

**In addition to the post-IRB VA approval process referenced above, there are also VA-specific items that must be addressed before IRB review. Failure to address the two VA components listed below will prevent your protocol from even receiving a full IRB review.

1. **VA information security and privacy Officer (ISO-PO) Approval:** This must happen before the IRB will move your protocol to full-board review. The ISO-PO approval process is initiated by submitting an ISO-PO checklist (accessible through the VA Forms link above) to the Baltimore VA Research Service. Personnel from the VA Research Office will then work to get the required approval signatures, ensuring that the signed ISO-PO checklist is uploaded as a public comment to your protocol's History Log. Again, your protocol CANNOT move forward to full IRB review without a fully signed ISO-PO checklist in the History Log, so getting that item submitted to the VA Research Service as quickly as possible should be a top priority.

2. **Specification of Research Activity Locations:** VA policy mandates that locations of all research activities (including data coordination, data analysis, and data storage) be clearly specified within appropriate sections of the CICERO protocol and the VA Informed Consent Document. Please ensure that locations of all research activities are clearly specified throughout these documents before submitting the protocol to IRB. This is particularly important for "VA Collaborative Studies" (i.e. those studies involving research activities that occur at both VA and non-VA sites). However, all studies, be they collaborative or not, should make clear delineation of research activity locations and data locations an emphasis.

2 **Questions answered on 'Organizational Review Requirements' page**:

The research will be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments):	**Yes**
The research will utilize VA resources (e.g. equipment, funds, medical records, databases, tissues, etc.):	**Yes**
The research will be conducted on VA property, including space leased to and used by VA:	**Yes**

Questions answered on 'VA Prohibited Research' page:

The research is planned emergency research in subjects from whom consent can not be prospectively obtained:	**No**
The study involves fetuses:	**No**
The study involves in vitro fertilization:	**No**
The research involves work with embryonic stem cells:	**No**
The study involves children AND is greater than minimal risk:	**No**
Recruitment phone calls involve asking veterans for their Social Security numbers:	**No**

If the answers to these questions are wrong, use the Jump To menu to return to the 'Organization Review Requirements' page to change your answers.

3 * **Confirm** - You have read the above information and understand that in addition to this IRB application form (CICERO), you are required to send a submission to the VAMHCS R&D Committee **within 60 days of receiving IRB approval**.

● **Yes** ○ No

ID: VIEW4E1C8F0D7B000
Name: v2_VA Review Required

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews -** Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews -** Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
Psych CMHSR General	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

HP-00072447

Additional Documents_V2

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
CITI Traing_Part 2_VA Human Subjects Protection.pdf(0.01)	12/14/2021 1:52 PM	12/14/2021 1:52 PM
CITI Traing_Part 1_Good Clinical Practice.pdf(0.01)	12/14/2021 1:52 PM	12/14/2021 1:52 PM
CITI CERT BEANS.pdf(0.01)	5/5/2021 3:52 PM	5/5/2021 3:52 PM
VA PRIVACY AND INFORMATION SECURITY AWARENESS BEANS.pdf(0.01)	5/5/2021 3:52 PM	5/5/2021 3:52 PM
MTTCS BEANS.pdf(0.01)	5/5/2021 3:52 PM	5/5/2021 3:52 PM
VA Privacy and Information Security Yoo(0.01)	5/5/2021 7:44 AM	5/5/2021 7:44 AM
Yoo Human Research GCP.pdf(0.02)	5/5/2021 7:40 AM	5/5/2021 7:43 AM
Yoo Biomedical Research Investigators and Key Personnel.pdf(0.02)	5/5/2021 7:40 AM	5/5/2021 7:43 AM
Privacy and HIPAA Training Yoo.pdf(0.02)	5/5/2021 7:40 AM	5/5/2021 7:43 AM
UMB COVID Risk Statement(0.02)	1/15/2021 11:43 AM	4/29/2021 11:16 AM
Phipps CITI Baltimore512 BASIC BMR 2018.pdf(0.01)	3/10/2021 3:11 PM	3/10/2021 3:11 PM
Phipps CITI Baltimor512 Basic 2018.pdf(0.01)	3/10/2021 3:11 PM	3/10/2021 3:11 PM
Brian Phipps Privacy HIPPA Training 2020.pdf(0.01)	3/10/2021 3:11 PM	3/10/2021 3:11 PM
2020. Brian Phipps _VA Privacy and Information Security Awareness and Rules of Behavior.pdf(0.01)	3/10/2021 3:11 PM	3/10/2021 3:11 PM
Notarfrancesco CitiTraining GCP Certificate .pdf(0.01)	3/10/2021 3:11 PM	3/10/2021 3:11 PM
Notarfrancesco CitiTraining Human Research Subjects Certificate.pdf(0.01)	3/10/2021 3:10 PM	3/10/2021 3:10 PM
20.11.24 VA Privacy and Security 2020-Notarfrancesco.png(0.01)	3/10/2021 3:10 PM	3/10/2021 3:10 PM
20.11.25 Privacy and HIPPA-Notarfrancesco.png(0.01)	3/10/2021 3:10 PM	3/10/2021 3:10 PM
Muralidharan 0920 reopening letter.pdf(0.01)	12/8/2020 4:31 PM	12/8/2020 4:31 PM
Follow Up Interview Info Sheet(0.02)	6/12/2020 12:07 PM	6/12/2020 4:33 PM
Jamie Giffuni CITI HSP(0.01)	11/8/2019 8:06 AM	11/8/2019 8:06 AM
Jamie Giffuni Privacy and Info Security(0.01)	11/8/2019 8:06 AM	11/8/2019 8:06 AM
Jamie Giffuni CITI(0.01)	11/8/2019 8:05 AM	11/8/2019 8:05 AM
Jamie Giffuni Privacy and HIPAA(0.01)	11/8/2019 8:05 AM	11/8/2019 8:05 AM
NOPP Acknowledgment(0.01)	9/14/2018 9:19 AM	9/14/2018 9:19 AM
NOPP(0.01)	9/14/2018 9:19 AM	9/14/2018 9:19 AM
HIPAA Privacy and Security Kinnera Atluri(0.01)	8/30/2018 3:58 PM	8/30/2018 3:58 PM
HIPAA Kinnera Atluri(0.01)	8/30/2018 3:58 PM	8/30/2018 3:58 PM
CITI VA Kinnera Atluri(0.01)	8/30/2018 3:58 PM	8/30/2018 3:58 PM
CITI Basic Kinnera Atluri(0.01)	8/30/2018 3:58 PM	8/30/2018 3:58 PM
Mastella CITI 2(0.01)	4/26/2018 8:08 AM	4/26/2018 8:08 AM
Mastella CITI(0.01)	4/26/2018 8:07 AM	4/26/2018 8:07 AM
Mastella HIPAA(0.01)	4/26/2018 8:07 AM	4/26/2018 8:07 AM
VAP_InfoFlyer_Aim1.docx(0.02)	5/31/2017 10:30 AM	5/31/2017 10:40 AM
VAP_InfoSheet_Aim1.docx(0.02)	5/25/2017 4:23 PM	5/31/2017 10:00 AM
EAP_InfoSheet_Aim1.docx(0.01)	5/25/2017 4:23 PM	5/25/2017 4:23 PM
ISOPO_Checklist_Signed.pdf(0.02)	11/7/2016 2:32 PM	4/28/2017 10:55 AM
Evaluation to Sign Consent- PEER.docx(0.01)	11/7/2016 10:34 AM	11/7/2016 10:34 AM
GRECC I-SMB policy_072016.doc(0.01)	10/31/2016 5:18 PM	10/31/2016 5:18 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

HP-00072447

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Psych CMHSR General	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Lorrianne Kuykendall

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lorrianne Kuykendall works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Melanie Fischer

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Melanie Fischer will be assisting with qualitative interviews and analysis for this study. She is knowledgeable about working with this population specifically older adults and adults with SMI.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Cynthia Giron-Hernandez

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Cynthia Giron-Hernandez works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Jeffrey Beans

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Jeffrey Beans is an exercise physiologist who will assist on the study. He is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Steven Yoo

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Steven Yoo is an exercise physiologist who will assist on the study. He is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Brian Phipps

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Brian Phipps is an exercise physiologist who will assist on the study. He is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Leslie Katzel

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Katzel has more than 25 years of experience conducting research and is well-versed in UMB and VA research practices and policies.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Richard Goldberg

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Richard Goldberg has been a member of the faculty within the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS for a number of years. He has served as the Principal Investigator or a Co-Investigator on numerous studies of mental health services interventions for individuals with serious mental illnesses. Dr. Goldberg has conducted or participated in research involving this population at the study sites where the proposed research will take place. He is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Gabriella Coakley

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Gabriella Coakley works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Belinda Kauffman

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Belinda Kauffman will be helping create study databases and determine data management procedures. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Laura Mastella

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Laura Mastella is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Jamie Giffuni

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Megan Kelly is an exercise physiologist who will assist on the study. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Lijuan Fang

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lijuan Fang is a statistician for the study and works with the study data. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Amanda Peeples

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Amanda Peeples has worked with the VA Maryland Health Care System as the Social Science Program Coordinator for over a year. She has worked on several other studies involving people with serious mental illnesses and has significant experience researching sensitive topics with vulnerable populations. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Steven Prior

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Prior has more than 10 years of experience conducting research and is well-versed in UMB and VA research practices and policies.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Kinnera Atluri

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Kinnera Atluri works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has experience working on clinical research projects. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Kelly Lloyd

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Kelly Lloyd works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Lynda Robey

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lynda Robey has many years of experience overseeing research and is well-versed in UMB and VA research practices and policies.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Clayton Brown

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Clayton Brown is a statistician for the study and works with the study data. He has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Howard Turner

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Howard Turner works with the VA Maryland Health Care System as a Peer Specialist and research team member. He has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. He is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Kirsten Harvey

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Kirsten Poston works with the VA Maryland Health Care System as a research team member. She has been specially trained in how to interact with individuals with serious mental illnesses and has worked on several other studies involving this population. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Tracy Robertson

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Tracy Robertson works with the VA Maryland Health Care System as a Peer Specialist and research team member. She has been specially trained in how to interact with individuals with serious mental illnesses. She is familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Alicia Lucksted

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Alicia Lucksted has been research faculty in the Psychiatry Department for more than 10 years. She has been the Principal Investigator or a Co-Investigator on numerous mental health services studies using quantitative, qualitative and mixed methods. Much of her past and current work involves the same or similar populations at the same or similar settings as the current proposed study. She is very familiar with the local and regional mental health and humans services systems, the proposed sites for this study, and the cultural and social contexts relevant to the proposed study.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
Jeanette Robinson

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Jeanette Robinson will be helping create and manage study databases and assis with data management. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

HP-00072447

IRB - Add a Team Member

Add a Team Member

1 * Select Team Member:
LAN LI

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lan Li is a statistician for the study and works with the study data. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.