UNIVERSITY of MARYLAND BALTIMORE

Date: Wednesday, December 21, 2022 8:49:00 AM Print Close

**HP-00063844** Introduction Page_V2

# Introduction Page

1 * Abbreviated Title:
PCC Recent Veterans

2 * Full Title:
Development of a Patient Centered Mental Health Intervention for Recent Veterans

3

* 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-00063844

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.***
Samantha Hack

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 | Alicia Lucksted | no | no | Research Team Member | no | ID00001635 |
| View | Lijuan Fang | no | no | Statistician | no | |
| View | Clayton Brown | no | no | Statistician | no | ID00000679 |
| View | Howard Turner | no | no | Research Team Member | no | |
| View | LAN LI | no | no | Statistician | no | |
| View | Belinda Kauffman | no | no | Research Team Member | no | ID00009489 |
| View | Gabriella Coakley | no | no | Research Team Member | no | |
| View | Lorrianne Kuykendall | no | no | Research Team Member | no | |
| View | Amy Drapalski | no | no | Research Team Member | no | ID00000269 |
| View | Jeanette Robinson | no | no | Research Team Member | no | ID00008752 |
| View | Melanie Bennett | no | no | Research Team Member | no | ID00006944 |
| View | Tracy Robertson | no | no | Research Team Member | no | |
| View | Cynthia Giron-Hernandez | no | no | Research Team Member | 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-00063844 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:
Samantha Hack, PhD will devote approximately 35 hours per week of her VA time to conduct and complete this research study.

2 * Describe the facilities where research procedures are conducted:
This project is being completed at the VA Maryland Health Care System (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 specially trained in working with participants with mental health disorders. Their assigned duties on this project will be described to them in detail prior to working with research participants. They will become very familiar with the protocol through ongoing study team meetings and trainings. All of our staff are extensively trained on obtaining informed consent, and the study assessment and study intervention. 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 and conducting the study assessment. Supervision for those conducting the manualized treatment intervention is also held on a regular basis by Samantha Hack, PhD.

*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**
- [x] **Procedures**
- [ ] Other

3 Please discuss any additional information regarding funding below:

*ID: VIEW4DF85DF452400*
*Name: v2_Funding Information*

HP-00063844

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:
Department of Veterans Affairs Rehabilitation Research & Development Service

* Address 1:
810 Vermont Avenue, NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20420

* Contact Person:
Tiffany Asqueri

* Phone Number:
202.443.5757

* Federal Agency Email:
Tiffany.Asqueri@va.gov

Grant Number 1 (if applicable):
1 IK2 RX002159-01A2- 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:

PI of Grant 2:

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-00063844 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*

# 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*

HP-00063844

Type of Research_V2

# 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).**
- [ ] 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-00063844** 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.

Project Background: The term “recent Veterans” refers to Veterans who served in the military operations Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn. Almost 60% of recent Veterans who received VA care have been diagnosed with a mental health disorder, most commonly posttraumatic stress disorder (32%), depressive disorders (26%), anxiety disorders (25%), and substance abuse (13%). The research literature consistently confirms that recent Veterans with stress-related mental health disorders experience impairment in functional domains of health (overcoming and managing disease), purpose (meaningful daily activities and participation in society), and community (positive relationships and social networks).

Project Objectives: The proposed research will characterize patient centered care in VA mental health care and produce a brief patient centered intervention that will empower Veterans to lead and personalize their mental health care in support of their functional recovery. In Aim 1 of this research we will characterize rates of providers’ and recent Veterans’ (n=35) participation in the four components of PCC, as well as barriers and facilitators of each PCC component, to inform development of a brief patient centered mental health intervention in Aim 2. In Aim 2 we will develop a brief patient centered mental health intervention for recent Veterans experiencing stress-related mental health disorders and conduct a pre-pilot demonstration (n=10) to assess acceptability. This intervention will be informed by data collected in Aim 1 and developed using an iterative process of discussion with and input from recent Veterans, VA mental health providers, peer specialists, and researchers. Finally, in Aim 3 we will test the feasibility and preliminary efficacy of the brief intervention by conducting a randomized controlled trial with 48 recent Veterans with stress-related mental health disorders.

*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:

Specific Aim 1: Characterize current rates of mental health providers' and recent Veterans' (n=35) participation in the four components of PCC, including barriers and facilitators to receipt of PCC components, to inform development of a Veteran-targeted, brief patient centered mental health intervention (PCI) in Aim 2.

Specific Aim 2: Use participatory action research methods with a stakeholder advisory panel, Veteran focus groups, and data collected in Aim 1 to develop a brief, Veteran-targeted PCI to facilitate engagement in mental health services for recent Veterans with stress-related mental health disorders and to conduct a clinical demonstration (n=10) of its acceptability.

Specific Aim 3: Conduct a pilot randomized controlled trial of the brief, Veteran-targeted PCI in a sample of recent Veterans with stress-related mental health disorders (n=48) to assess feasibility and preliminary efficacy.
Hypothesis 3a: The brief PCI will be shown to be feasible as evidenced by successful rates of recruitment, attendance at intervention sessions by Veterans, and interventionist fidelity to the intervention.
Hypothesis 3b: Compared to a health and wellness control intervention, participation in the brief, Veteran targeted PCI will result in significant increases in (1) Veteran PCC behaviors in mental health care encounters and (2) functioning in domains of health, purpose, and community.
Secondary analysis: Comparing the RCT arms, explore (1) Veteran attrition from VA mental health care via chart review and (2) Veteran self-assessment of levels of clinical symptomology with the DASS-21, AUDIT, DAST 10, and PCL-5.

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: 35 recent Veterans with stress-related mental health disorders and their VA mental health providers will consent to audio-recording of one treatment encounter. (There is no randomization or group assignment.)
Aim 2: Two focus groups of 4-6 Veterans each will be held. We will also conduct a clinical demonstration of the PCI with 10 Veterans to examine acceptability and further refine the intervention. Participants will complete the three session intervention and participate in a qualitative interview about their experience. (There is no randomization or group assignment.)
Aim 3: We will conduct a pilot randomized controlled trial of the PCI (n=48) to assess feasibility and preliminary efficacy. 24 participants will be randomized to a health and wellness control condition and 24 to the experimental treatment condition.

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

Veteran preferences vs. actual PCC behaviors. As a MIRECC Fellow, I have analyzed data from an RCT of a computerized intervention to assist Veterans with serious mental illness (SMI) in receiving recommended monitoring for metabolic side effects of second-generation antipsychotic (SGA) medications (PI: J. Kreyenbuhl). Veteran participants age 18 to 70 with an SMI (including major depression and PTSD) and who were currently prescribed one or more oral or injectable second generation antipsychotics by a psychiatrist or
nurse practitioner (NP) were recruited from two VA outpatient mental health clinics in the VAMHCS. Participants completed assessments of psychiatric symptom severity, therapeutic alliance, shared decision making, visit satisfaction, and ability to self-advocate about one's concerns. Audiotaped interactions were coded using the Roter Interaction Analysis System (RIAS), a widely used and validated system of coding provider-patient communication.43-45 The system assigns each utterance expressed by the patient and provider to one of 41 mutually exclusive and exhaustive categories.46 I used these data to compare responses from self-identified African American (n=83) and White (n=81) Veterans on preferences for involvement in care and actual involvement in care.

Veteran preferences for involvement in care. First, there were no racial differences in perceptions of prescriber rapport with Veterans or support from prescribers. However, African American Veterans were more likely to perceive that their prescribers withheld the truth or were authoritarian and impatient. There was no significant racial difference on Veterans' assessments of their ability to self-advocate about their concerns with their prescribers. There were, however, differences by race in preferences for shared decision making.
Specifically, African American Veterans were less likely to prefer relying on their prescribers for decisions about their mental health care than White Veterans, and were more likely to feel that their prescribers encouraged high levels of patient participation in the decision making process.

Veterans' actual involvement in care. Second, while self-evaluation provides valuable information about Veteran preferences for and perceptions of mental health care interactions, the use of the RIAS also allowed comparison of survey responses to behaviors in actual appointments. Analyses of the recordings found that African American Veterans had shorter appointments (18.6 minutes, SD=10.8) compared to White participants (22.4 minutes, SD=11.9; p=.034). Notably, this difference seemed to be solely linked to differences
in patient behaviors, not prescriber behaviors. There were no differences associated with race in the amount or type of prescriber statements. However, African American Veterans spoke less than White Veterans, (average 25 fewer statements per 15 minute interval). Specifically they had significantly lower rates of psychosocial information giving, emotional rapport, and procedural statements, and were less likely to express disagreement or criticism to their prescriber. The difference was greatest in psychosocial information giving, where African American Veterans made 10 fewer statements per 15 minutes about lifestyles or psychosocial environment.

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

Recent Veterans are at significant risk of experiencing stress-related mental health disorders such as PTSD, depression, anxiety, and substance use disorders, and subsequently, difficulties in health, home, purpose, and community functioning. Research indicates that recent Veterans in VA treatment for stress-related mental health disorders have unacceptably high dropout rates and that such
Veterans would prefer personalized mental health care that supports their functional recovery. Simultaneously, the VA has begun a system-wide transformation with the goal of moving from disease centered care to personalized, proactive, PCC. Based on my preliminary research (presented in section 2), Veterans have the desire to be actively involved in their mental health care but do not typically achieve the level of participation they want. This is in keeping with research that interventions that change patient behaviors and engagement are most effective at improving the patient centeredness of care and functional outcomes. While the VA has introduced provider-focused PCC training interventions, no Veteran-targeted PCC interventions exist to prepare Veterans to engage collaboratively with VA providers. We lack both knowledge about what barriers are impeding Veteran engagement in PCC and an intervention to increase Veteran engagement in mental health care and support recent Veterans' functional recovery from stress-related mental
health disorders. This proposal will directly address this knowledge gap first by gathering foundational knowledge about Veteran and provider PCC behaviors in VA mental health care. I will accomplish this by coding and analyzing recordings of provider-recent Veteran mental health care encounters (n=35) to identify behaviors that facilitate and inhibit PCC in VA mental health care, in order to develop a targeted intervention. Second, I will partner with Veterans, VA providers, and VA researchers to develop and pilot a brief, Veteran-targeted
patient centered mental health intervention (patient centered intervention; PCI) led by a member of the research team to educate Veterans about PCC, help them identify their treatment goals, and catalyze their involvement in treatment planning. I will conduct a clinical demonstration (n=10) of the PCI to examine acceptability and further refine it and then a pilot RCT (n=48) to assess feasibility and preliminary efficacy. This PCI will support the expansion of VA PCC to mental health care settings, and VA PCC initiatives generally.

# 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.***

Recent Veterans experience high rates of stress-related mental health disorders. The term "recent Veterans" refers to Veterans who served from 2001 to the present day, in Afghanistan and Iraq in the military operations Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn1 (OEF/OIF/OND). They are a fast growing group seeking services at VA: as of 2014, over 1.1 million have accessed VA care1. Recent Veterans have experienced significant combat and trauma exposure, leading to high rates of stress-related mental health disorders.2, 3 'Stress-related mental health disorders' is an umbrella term used by VA programs such as Services for Returning Veterans-Mental Health (SeRV-MH) and the Center of Excellence for Stress and Mental Health (CESAMH) to describe negative mental health responses to the stress of military or combat service. As in this application, it is typically conceptualized as posttraumatic stress disorder, anxiety disorders, depressive disorders, and substance use disorders. According to a recent VA
report1, of the 1,126,173 recent Veterans who received VA care, 60% (640,537) were diagnosed with a mental health disorder, stress-related mental health disorders are among the most common: 32% were diagnosed with PTSD, 26% with depressive disorders, 25% with anxiety disorders, and 13% with substance use disorders. These disorders commonly co-occur, amplifying Veterans' experiences of psychiatric symptoms and the negative social, emotional, and functional impacts4.

Stress-related mental health disorders critically impact functional reintegration. The US Substance Abuse and Mental Health Services Administration, describing recovery from mental health disorders, identified four dimensions of functioning: health, home, purpose, and community5, p.3. The home dimension indicates "having a stable and safe place to live". Health functioning includes managing one's diseases and making informed choices. Purpose in recovery is marked by meaningful daily activities related to responsibilities such as family, work, or volunteering. Community functioning entails maintaining rewarding relationships and social networks. Attaining and maintaining these four dimensions is complicated for recent Veterans by difficulties reintegrating into civilian life after overseas combat assignments and years in military culture6. The combination of stress-related mental health disorders and reintegration adjustments creates significant barriers for recent Veterans resuming their roles as civilian partners, parents, employees, and community members. Recent Veterans with mental health disorders experience functional impairment in numerous domains. For example, Veterans with PTSD, depression, or anxiety report lower self-efficacy in purpose and community functioning7. Among recent Veterans who completed the Community Reintegration for Service Members instrument, those with mental health disorders scored more poorly than those without on all three subscales: extent of participation, perceived limitation in participation, and participation satisfaction8. Recent Veterans who have accessed VA services report poorer physical and mental health than the general population and 40% report at least some difficulty reintegrating in civilian life; Veterans experiencing symptoms indicative of PTSD report even greater readjustment difficulties9. Recent Veterans experience higher unemployment than both non-Veterans and older Veterans10 and have an increased likelihood of homelessness due to behavioral health factors11. In a sample of recent Veterans referred for behavioral health evaluations, 75% of those living with family members or significant others reported family problems in the last week12. In the most dramatic example of functional impairment, when compared to other recent Veterans, recent Veterans with PTSD or subclinical PTSD have higher rates of suicide ideation and attempts, especially when co-occurring with depression or substance abuse disorders13, 14. Research is consistent and conclusive: recent Veterans experiencing stress related mental health disorders have more difficulty maintaining healthy social networks and interpersonal relationships, are less likely to successfully participate in activities such as work or school that give people a sense of purpose, and are at higher risk of experiencing extreme difficulties such as homelessness or hopelessness leading to suicide. Successfully treating recent Veterans' stress-related mental health disorders and supporting their recovery and civilian reintegration is one of the most important tasks facing the VA.

The PCC model. Patient centered care (PCC) is a critically important tool in successfully addressing stress-related mental health disorders among recent Veterans. The Institute of Medicine16 defines PCC as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." In The Blueprint for Excellence, the VA describes PCC as "care that is personalized, proactive, and patient-driven, and engages and inspires Veterans to their highest possible level of health and well-being" 17, p.26 . The Blueprint promotes PCC as one of the 10 essential strategies for the evolution of VA care. These definitions represent aspirational goals and a philosophical approach to PCC but fail to explicate the interventions or behaviors necessary to achieve patient centeredness in treatment. de Silva18 examined the empirical literature and found two ways of conceptualizing PCC: either as a holistic concept or as isolated sub-concepts thought to contribute to PCC (e.g. patient satisfaction, patient engagement, provider empathy). However, unilaterally equating sub-concepts with holistic PCC complicates
researchers' and clinicians' understanding of how to provide PCC and gauge its efficacy. That is, even if Veterans report they are satisfied with care, and satisfaction is an element of PCC, we cannot assume that we are providing PCC. To address this issue, Stewart and colleagues19 have constructed a model of PCC that identifies four key components. Figure 1 illustrates them and the behaviors or information that comprises each. This model provides both holistic and component conceptualizations of PCC and operationalizes each component with behaviors, information, or existing, well-defined concepts. This definition of PCC facilitates researchers' ability to quantify, measure, and evaluate levels of patient centeredness in care, while also providing a theoretical foundation for developing interventions to achieve the holistic experience of PCC. Moving forward, we will cumulatively refer to such behaviors, information, or concepts as PCC behaviors.

PCC and improved outcomes. PCC improves patient satisfaction, treatment adherence, and treatment outcomes20,81. Though much of the current PCC literature examines PCC in physical health care settings, it does provide indicators that PCC could improve therapeutic alliance and clinical outcomes in mental health care. Saha and Beach21 asked patients to view and rate video vignettes of patient centered and non-patient centered cardiology encounters. Patients rated patient centered providers as more trustworthy and competent
and were more likely to say they would accept the provider's recommendation and undergo bypass surgery. Rathert and colleagues'92 systematic review found "mixed results for long-term clinical outcomes"p. 373 noting that studies which accounted for variability in provider PCC behaviors more often found positive relationships between PCC and clinical outcomes than those that did not. Etingen and colleagues'93 recent examination of 5,512 VA patients found PCC positively correlated with clinical indicators of good chronic condition
management and appropriate health care use. McMillan and colleagues22 conducted a systematic review of randomized controlled trials (RCTs) of PCC interventions for people with chronic illnesses. They concluded that changing provider behaviors was "unlikely to be effective, but simple interventions designed to increase patient empowerment and active engagement" had a positive impact on outcomes p.586. They also observed that PCC was successful at improving functional outcomes: 11 of 12 reviewed studies showed significant functional improvement in areas such as improved emotional well-being, performance in activities of daily living, independence, and reduced role limitations. However, most patient centered research and intervention testing has occurred in physical health or integrated health care settings and not in mental health care settings, this is a significant knowledge gap. Nonetheless, these consistent findings of the benefits of PCC in physical health care support the potential impact of patient centered mental health care. Further they suggest that a PCC intervention targeted at empowering Veterans to be more activated and participatory in mental health
care encounters will have a positive impact on functional outcomes.

PCC in VA. As previously noted, PCC has been established as a guiding policy in the VA. This is in keeping with VA efforts, since 2003, to move to recovery-oriented mental health care, "a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential"5. VA recovery-oriented programs have produced positive results: among Veterans with a history of long inpatient psychiatric hospitalizations, multiple decades for almost half of the participants, Veterans who completed the recovery-oriented program had greater community tenure and fewer hospital admissions82. In another study, Veterans who participated in a recovery-oriented, active peer, case management group intervention had greater community functioning and acquired Section 8 housing vouchers more quickly83. SAMHSA84, Corrigan85, 86, and others87 have noted that order to be successful as a recovery-oriented system of care organizations must focus on patient self-determination facilitated via patient-centered care. Led by the Office of Patient Centered Care & Cultural Transformation (OPCC&CT), VA's initial PCC efforts have focused on physical health clinics, and primarily roll out efforts for: 1) the Personal Health Inventory (PHI), an instrument for Veteran self-assessment and health goal setting, which will be modified for use in mental health care settings as part of this intervention development (see Appendix 5. Intervention materials)23; 2) Whole Health, a training to build provider PCC skills24; and 3) Patient Aligned Care Teams (PACTs), a teambased
approach to primary care25. Researchers conducting program evaluation at four VA medical systems that have been designated as Centers of Innovation (COIs) noted the importance of engaging Veterans in PCC through formal and informal programs and that staff need assistance in incorporating PCC into regular clinical interactions26. Additional qualitative evaluation was conducted at two of the COIs from 2013-14 to understand how such programs are implemented and how Veterans responded. Bokhour and colleagues23 found that providers struggled with shifting between PCC and more clinical questions and that it was "critical" to orient Veterans to the PCC process. Researchers observed that moving from disease-focused questions to person focused questions without explanation made Veterans "…visibly sad or embarrassed… confused and frustrated"p.6. The authors also noted that Veterans had difficulty answering the PCC questions without preparation and time to reflect on their answers, resulting in appointments taking longer than intended or
providers reducing the number of PCC questions they asked. Thus implementing PCC must be done with care; it is critical to prevent negative patient-provider

encounters by orienting Veterans to PCC and allowing them time to reflect on their goals and priorities. Additionally, the authors noted that providers modified the PHI tool to better serve their specific clinics and patient populations, highlighting that PCC approaches must be tailored. The work proposed here will address these issues both by developing a process for Veterans to learn about PCC and apply it to their personal goals, as well as by tailoring the PHI for use in mental health clinics.

Patient centered mental health care. While PCC is being formally implemented in some VA primary care and specialized physical care clinics, there are currently no explicitly PCC-grounded interventions offered in VA mental health care. This is in keeping with non-VA mental health care where PCC is also still an emerging approach to clinical practice27, 29. Mental health care providers examining PCC will find similarities with the philosophy of recovery-oriented mental health care and high compatibility between them. “Recovery refers to
the process in which people are able to live, work, learn, and participate fully in their communities” and PCC Initial research in patient centered mental health care has produced promising results but also illustrates the need for patient-focused interventions. Epstein and colleagues30 covertly recorded provider encounters with standardized patients portraying a person with major depression or adjustment disorder at a range of levels of patient activation. They analyzed patient and provider behaviors using an adaptation of the Measure
of Patient-Centered Communication, a coding tool that will be used in this research. Providers exhibiting high PCC behaviors were more likely to prescribe anti-depressants and to do so based on clinical indicators, whereas providers rated low in PCC behaviors were more likely to prescribe as the result of direct patient requests. Simon and colleagues31 tested a patient centered intervention for people with bipolar disorder in which nurse care managers provided education about managing bipolar disorder, monitored patients’ symptoms, and provided feedback to the mental health treatment teams. The intervention was found to be associated with reduced mania symptoms and duration of manic episodes, though it did not impact depressive symptoms. However, this intervention did not target patient behaviors in treatment interactions, and in fact placed the nurse manager as the liaison between clinicians and patients, raising questions about the
intervention’s degree of patient centeredness. Blonigen and colleagues32 tested a patient centered intervention with Veterans entering residential treatment for substance use disorders. Patients first worked with an interventionist to determine what they wanted to learn about themselves and what behaviors they wanted to change. With that guiding information, the interventionist then conducted personality testing, shared the results, and elicited patients’ participation in the process of interpreting and applying the results to treatment planning. Patients who received the intervention reported strong satisfaction with treatment and experienced stronger therapeutic alliance and more positive relationships with other residents. Taken together, this small but growing literature illustrates the ways that patient centered mental health care interventions focused on increasing patient participation in care and patient-provider collaboration can improve satisfaction and treatment outcomes. VA mental health care for stress-related disorders will benefit from a transformation in line with a PCC model. Despite the high rates of stress-related mental health disorders among recent Veterans, research has shown that only a small portion of recent Veterans experiencing these disorders attend enough mental health treatment sessions to satisfy VA treatment recommendations for recent Veterans with PTSD (at least eight sessions over 14 weeks following initial diagnosis)33. In a sample of 600 recent Veterans with mental health disorders (predominantly PTSD, substance abuse, depression, and adjustment disorders) 429 Veterans (72%) accepted a referral to specialty mental health care, 229 (38%) attended at least one appointment within a year of referral, and only 113 (19%) attended eight or more mental health care appointments within a year of referral34. Grossbard and colleagues found that in a sample of recent Veterans with severe alcohol misuse (n=411), depending on co-occurring diagnoses, only 14-41% accepted a referral to substance abuse treatment35. In a systematic review of dropout from PTSD treatment among recent Veterans, Goetter, and colleagues found that the average dropout rate across 20 studies was 36%.36 This is in keeping with quality improvement data collected locally from the VAMHCS Trauma Recovery Program (TRP) which evaluated
Veteran completion of Cognitive Processing Therapy or Prolonged Exposure, the VA’s recommended evidence based practices (EBPs) for PTSD, over four months in 2012-13. They found that of the 61 Veterans referred forEBP PTSD treatment, 39 Veterans (64%) did not complete the recommended 8 treatment sessions (personal communication, E. Romero, October 28, 2015). PCC interventions that help recent Veterans connect participation in mental health treatment with their own goals and priorities have the potential to increase rates
of treatment engagement and completion.

Recent Veterans want PCC. Recent Veterans experiencing stress-related mental health disorders report that they want personalized mental health services that support their functional recovery and successful reintegration into their civilian lives. Sayer and colleagues9 found that 96% of recent Veteran respondents were interested in community reintegration services and those with probable PTSD wanted a broader array of rehabilitation-focused mental health services. Crawford and colleagues15 reported that when asked about their
preferences for 25 possible interventions, 80% of recent Veterans expressed interest in multi-faceted mental health services that addressed co-occurring problems with stress, anger, sleep, pain, and readjustment: Recent Veterans who had already used VA mental health services were more likely to report wanting the VA to provide family services as well. While these Veterans were not using the term “PCC”, they were describing it: care that is personalized to their experience, focused on improving outcomes that are personally meaningful, and directed by their own preferences and priorities for recovery.

**2** If available, upload your applicable literature search:

| Name | Created | Modified Date |
|---|---|---|
| Literature(0.01) | 10/18/2016 5:17 PM | 10/18/2016 5:17 PM |

*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: data will be collected at one time point using surveys and an audio recording of a Veteran/provider encounter which will be sent to an outside transcription agency to be transcribed, and then coded to quantify Veteran and provider patient centered care behaviors.

Following the recorded Veteran/provider encounter, participants will have the option of completing the surveys in person or taking the surveys and a pre-addressed, stamped envelope and returning the surveys at a later time. If participants have not returned the surveys within one week a study team member will follow-up by phone and offer to conduct the surveys by phone. Participants will be mailed their participation compensation funds upon receipt of the survey data.

Aim 2: Intervention development will be led by a multi-stakeholder Expert Advisory Panel and further developed using Veteran focus groups. Acceptability will be demonstrated via qualitative interviews following a pre-pilot demonstration project with 10 Veteran participants. Ten Veteran participants will receive the intervention. There will be no randomization or control condition. Veterans will complete survey measures after consenting to participate in the trial. Following participation in the intervention the Veteran participants will complete survey measures and a qualitative interview face-to-face.

Following conclusion of Aim 2, the Expert Advisory Panel (EAP) will discuss the results of Aim 1 and Aim 2 as a group and determine if any changes need to be made to enhance utility or improve intervention delivery prior to Aim 3. To determine readiness to proceed to Aim 3, the EAP will hold an anonymous vote during EAP Meeting 4. At least 75% of present EAP members must approve the intervention to move into randomized controlled trial (RCT) testing before Aim 3 will commence. If the EAP does not vote to proceed, the research team will make recommended modifications, present the updated intervention at a new meeting, and the EAP will vote again to proceed. If necessary this process will continue until the EAP approves the intervention for testing in the pilot RCT. A modification reflecting the final intervention will be submitted once the intervention has been finalized.

We will use VA email to communicate with EAP participants in order to facilitate scheduling and sending reminders and/or materials for the final EAP meeting. This meeting will be held in person or via telehealth/phone depending on participant comfort and safety as it relates to COVID-19. If the meeting is held in person, the COVID-19 risk form will be reviewed with all attendees to ensure understanding. Staff will discuss proper procedures for communication via email with the veterans ahead of time to ensure understanding. The emails will also include a clear statement that no completed forms or personal identifying information should be sent to staff via email correspondence. For instance,

Signature for sign-off
Email is not secure. Please do not reply back to this message with any personal information or personal health information.

If you are having thoughts of harming yourself, please call the Veterans Crisis Line at 1-800-273-8255.

* Confidentiality Notice *
This electronic message may contain confidential and legally protected information, intended only for the use of the individual or entity named in the message header. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this electronic message and/or any attachments is strictly prohibited. If you have received this electronic message in error, please notify the sender immediately to arrange for your electronic email address to be removed from the sender's personal address book and/or distribution list.

1. Email script for EAP reminder

Subject: EAP appointment reminder

Reminder: The final EAP meeting will be held on DATE at TIME. Please call [staff] at XXX-XXX-XXXX if you have questions.
- If your appointment is by phone, [staff] will call you at the specified date and time.
- If your appointment is by telehealth you should have received a link to your email to access the appointment. If you have not or have questions, please give [staff] a call at XXX-XXX-XXXX
- If your appointment is in person and you would like to confirm the location, please contact [staff] at XXX-XXX-XXXX

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

2. Email script for EAP scheduling

Subject: research study follow up

Hello,
We're following up about your participation in a VA research study. It's time to schedule our final meeting so we can update you on our progress. Please use the following link to show when you are available for this meeting. If you have any trouble with the scheduling link or would like speak with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!

3. Email script 2 for EAP scheduling

Subject: research study follow up

Hello,
We're following up about your participation in a VA research study. Based on everyone's availability, we are hoping to schedule the meeting for DATE at TIME. The meeting will take place at LOCATION (phone/telehealth/in person). Please reply YES or NO to this email to confirm this works for you. If you had any trouble with the scheduling link or would like speak with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX. We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!

Aim 3 quantitative data will be collected at baseline, post-RCT participation, and 3 month and 6 month follow-up and qualitative data will be collected at 3 month or 6 month follow-up. Feasibility will be assessed with study administration data on engagement and participation in the intervention and preliminary efficacy will be evaluated via coded Veteran/provider encounters and quantitative analysis of functioning from self-report surveys. Further needed intervention modifications will be identified from qualitative interviews.

Participants will have the option of completing the surveys in person, by phone, or by mail. If participants completing the surveys by mail have not returned the surveys within one week a study team member will follow-up by phone. Participants completing the surveys by phone or mail will be mailed their participation compensation upon receipt of the survey data.

We will use VA email to communicate with potential veteran participants and veteran participants during the acceptability trial and the RCT in order to recruit participants and send electronic copies of resources, blank worksheets, and/or response cards for them to use at a later time. When sending any documents for the initial consent appointment we will use a VA-approved method in order to encrypt the email message and add this extra security measure. We will only send follow up emails and/or these materials at the veteran's request and staff will discuss proper procedures for communication via email with the veterans ahead of time to ensure understanding. The emails will also include a clear statement that no completed forms or personal identifying information should be sent to staff via email correspondence. For instance,

Signature for sign-off
Email is not secure. Please do not reply back to this message with any personal information or personal health information.

If you are having thoughts of harming yourself, please call the Veterans Crisis Line at 1-800-273-8255.

* Confidentiality Notice *
This electronic message may contain confidential and legally protected information, intended only for the use of the individual or entity named in the message header. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this electronic message and/or any attachments is strictly prohibited. If you have received this electronic message in error, please notify the sender immediately to arrange for your electronic email address to be removed from the sender's personal address book and/or distribution list.

Potential participants

1. Email script for potential participants

Subject: research study eligibility

Hello,

I am on a research team that studies mental illness at the VA Maryland Health Care System. Currently, we are conducting a research study about ways to improve VA mental health care.

We would like to let you know that we believe you may be eligible for one of our studies. Your participation is entirely voluntary. If you do not want to participate, you will receive the same quality of care currently available to you. If you agree to participate, you will be reimbursed for your time and effort.

If you would like more information about this study, please respond to this email with YES OR call [staff] at XXX-XXX-XXXX.

If you do not want us to contact you, please respond to this email with NO.

If you do not respond we will contact you by phone to follow-up on this letter.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

2. Email script for potential participants who ask for more information via email

Subject: research study eligibility

Hello,
Per your request, here is information on the VA research study you are eligible for.

The study involves several types of appointments which take 6 hours of time split over multiple remote visits. We are currently conducting all visits over the phone and through encrypted, secure video chatting. To complete these appointments, you will need a computer/tablet with a microphone and camera or a smart phone.
In the first appointment we would complete the informed consent paperwork for this study and have you complete a few questionnaires (1-1.5 hours).
You would then be matched with a study interventionist who will call you to schedule your individual meetings. You would meet three times for individual educational meetings where you will learn about patient-centered health care. These meetings can be scheduled during times that are convenient for you and would take about 1 hour per session. All visits with study interventionists will be conducted through encrypted, secure, telehealth video conferencing. Approximately three and six months after the individual sessions are done you will complete study questionnaires. These would take about 45 minutes each. Each of the four times you complete questionnaires you will be compensated $50 for a total of $200 for your time. This payment will arrive in the form of an emailed gift card to Safeway or a check in the mail.

If you are interested in hearing more specifics, please respond with a good time to call you or call [VA staff] at XXX-XXX-XXXX. If you are no longer interested, please respond to this email with NO.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!

3. Email script for potential participants who have expressed interest in study participation
Subject: research study eligibility
Hello,

As you requested, we're following up about your interest in participating in a VA research study.
If you would like to schedule a time to meet with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

4. Email script for consent reminder with docs attached (encrypted email)

*The below message will be sent via encrypted email*

Subject: appointment materials

Hello,
We're following up as discussed about your initial appointment for the study. As requested, attached are blank electronic copies of the paperwork we will be discussing during that appointment. Our call is scheduled for [day], [date] at [time]. Research staff will call you at your preferred number. Please contact the research study team at XXX-XXX-XXXX if you have any questions prior to our phone call or if you need to reschedule.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

Omnis Salutis Study Team

Enrolled participants:

5. Email script for study appointment reminder

Subject: appointment reminder

Reminder: You have a visit on DATE at TIME. Please call XXX-XXX-XXXX if you need to reschedule or have questions.
- If your appointment is by phone a member of the study team will call you at the specified date and time. You can call XXX-XXX-XXXX to confirm the telephone number they will call you at or from.
- If your appointment is by telehealth you can consult the attached instructions for using VA telehealth.
- If your appointment is in person and you would like to confirm the exact location, please contact XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

6. Email script for study appointment materials
Subject: appointment materials

Hello,

Attached are materials for an upcoming appointment. Please have them visible to you during your appointment. You do not need to complete these materials before the appointment. These materials do not contain any personal health or identifying information.

Please call XXX-XXX-XXXX if you need to reschedule or have questions. We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

7. Email script for electronic copies of intervention materials
Subject: blank materials
Hello,

As you requested, attached are blank electronic copies of the materials we discussed. These materials do not contain any personal health or identifying information.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

8. Email script for participant payments
Subject: payment
Hello,

As we discussed, attached are two $25 gift cards, for a total of $50. If you have any questions please call XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

9. Email script for participants re: scheduling appointment

Subject: research study follow up

Hello,
We're following up about your participation in a VA research study. It's time to schedule your next assessment. If you would like to schedule a time to meet with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!

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

**3** * Describe the duration of an individual participant's participation in the study:
Aim 1: Approximately 2 hours
Aim 2: Approximately 10 hours for Expert Advisory Panel participants. Approximately 2 hours for focus group participants. Up to 6 hours for acceptability trial participants
Aim 3: Approximately 8 hours

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

**5** * Describe any additional participant requirements:
Not applicable.

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:

The primary goal of the Aim 3 pilot RCT is to assess the feasibility of PCI for a larger confirmatory RCT. After considering time and resources available with this CDA-2, we believe it will be feasible to randomize 24 individuals per condition. We expect 20% of those randomized in each condition will miss data collection at TP3, and 30% at TP4. This sample size will not be sufficient to detect "small" clinically important differences at TP3 (post-treatment) with 80% power as would be expected of a larger confirmatory RCT. However, with the anticipated 19 participants per condition with complete data at TP3, power is estimated to be equal to .80 for detecting between "medium" and "large" effect sizes (d=.65) with the ANCOVA analysis, assuming TP1 to TP3 or TP4 correlation in the response variable is r=0.7.

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 1 data analysis.
Audio recordings of Aim 1 will not be transcribed as outlined in Aim 2. Recorded Veteran-provider encounters will be coded by research staff using the Measure of Patient-Centered Communication (MPCC). Theoretically grounded in Stewart et al.'s model of patient-centered care, the MPCC is a method for trained raters to assess and quantify recordings of patient-provider encounters. It does not necessitate that the recorded encounters be transcribed for coding. The MPCC has been used to code many types of patient/provider encounters including care for acute and chronic conditions, routine physicals, follow-up visits and emergency department encounters.

After all survey and coding data has been captured into the database, frequency tables for all variables and histograms for continuous variables will be examined. Missing data and potential errors will be investigated and resolved. Scales and subscales will be scored. Normal Q-Q plots will be examined for continuous variables to check normality, skew, and to assess whether transformations are needed to examine the associations. Descriptive statistics will be calculated on demographic variables to characterize the sample. To assess PCC behaviors, descriptive statistics will be calculated for all PCC subscales and variables from coding, including: minimum, 25th percentile, median, mean, 75th percentile, maximum, and standard deviation. The descriptive statistics will be collected and displayed in tables separately for Veterans and providers along with histograms to visually assess overall distributions and variability. For these analyses, each patient-prescriber dyad will be treated as a unique encounter. Proportions of patients and providers meeting certain levels of the 4 components of PCC will also be calculated along with 95% confidence intervals.

Aim 2 data analyses
Aim 2 Veteran focus groups and refinement of materials. Once a draft of the PCI is developed, two focus groups of 4-6 Veterans each will be held (1-1.5 hours each. The focus groups will be led by the PI and observed by the coordinator, who will also take observational notes. Participants will be asked to comment on and critique the draft PCI structure and content. Because the goal is to elicit concrete suggestions and feedback with which to develop the PCI, focus group transcripts will not be coded to identify overarching themes or quotes. Rather they will be used to identify suggestions for PCI modification. Study team members will utilize the transcripts, observational notes, and personal observations to summarize focus group discussion and suggestions from focus group participants into an organized document for the EAP. In addition, relevant study team members will present the findings and be available for questions during EAP Meeting 3.

Aim 2 clinical demonstration of the PCI. The final task in Aim 2 will be to complete a clinical demonstration of the PCI (in its form after Meeting 3 input is incorporated) to examine acceptability using qualitative interviews. Participants will be 10 recent Veterans with current stress-related mental health diagnoses. The interventionist will be the same interventionist who will deliver the PCI in Aim 3. The
purpose of the clinical demonstration is to identify PCI features or materials that appear functional in theory but do not execute well in a clinical setting. At the end of their participation in the clinical demonstration, each Veteran will complete a qualitative semi-structured interview that will discuss their experience with the PCI and their thoughts about its overall utility. The interview will ask for feedback about the PCI content, materials, scheduling, and experience. This will include review of the format and content of the sessions,
handouts, and educational materials. Questions will focus on the participants' reactions to the content, including utility and clarity. Interviews will begin with broad open questions about initial reactions, explore those thoroughly, and subsequently ask specific follow up questions to elicit information about each facet of the intervention. After each interview the interviewer will append a field note documenting pertinent observations. Interviews will be in-person and recorded for verbatim transcription to facilitate coding.

Aim 2 analysis of semi-structured interviews. We will use qualitative RAP to analyze the semi-structured interviews. RAP is ideal for PAR studies with action-oriented goals: it uses team-based coding and focuses data analysis in order to answers to specific research questions.

Aim 3 data analysis.
First, summary statistics of demographic, clinical, and baseline outcome scale scores will be calculated for the total sample and compared between treatment groups to check the success of the randomization and for outliers. If there is an out-of-balance variable that is plausibly a prognostic factor for PCI outcome, we will adjust for this variable when comparing the two treatment arms. Nesting of multiple patients within the same provider will be identified.

Appointment recording coding. Similar to the procedures described in 3b11 (Aim 1 data analysis), the PI will work with two research team staff members to code recorded appointments with the MPCC. We will all code the first 4 recordings to confirm coder competence and establish interrater reliability. After the first 4 recordings coders will code recordings individually until every seventh recording. Every seventh recording I and the research team members will again all code the same recording and check for agreement. Through this process 20% of the recorded appointments will be coded and compared by multiple coders.

Aim 3, hypothesis 3a. The brief, Veteran-targeted, PCI will be shown to be feasible as evidenced by adequate rates of recruitment, Veteran attendance at PCI sessions, and interventionist fidelity to the PCI. We will track: (1) actual recruitment compared to recruitment goals; (2) number of sessions each participant attends, enabling us to identify initial engagement, overall attendance rates, and drop-out; (3) number of reminder and outreach contacts required to keep participants engaged, indicating how much staff time is required to successfully facilitate involvement; (4) interventionist adherence to the PCI; and (5) qualitative feedback from a subsample of pilot RCT intervention arm participants as described in section 3d9. Recruitment feasibility will be assessed by a proportion equal to # of patients who sign consent / # of patients approached. To account for sampling variability we will also calculate a 95% confidence interval. Attendance will be collected at each PCI session and stored in our database. We will calculate the proportion of sessions attended for each participant. Feasibility will be demonstrated if at least 80% of PCI participants attend at least 2 out of 3 of PCI sessions. Interventionist fidelity will be measured by our interventionist adherence rating scale. A random selection of 25% of the PCI session recordings will be analyzed, stratified by month over the course of the pilot RCT, to examine potential changes in the way the PCI
is delivered over time. After study completion we will calculate overall percentages for each item of the scale to assess overall fidelity. Interventionist fidelity will be demonstrated if at least 90% of interventionist behaviors in the analyzed PCI sessions have been rated acceptable or excellent.

Aim 3, hypothesis 3b. We hypothesize that compared to control participants, participation in the brief, Veteran-focused, PCI will result in significantly greater increase in (1) Veteran PCC behaviors in mental health care encounters as measured by the MPCC and (2) functioning in domains of health, purpose, and community as measured by the VR-36 and WHODASS. Our overall approach will be to compare group means using a mixed model, accounting for common providers among participants with a random provider effect. If
an out of balance prognostic covariate is found in baseline comparisons this variable will also be included in the model, although the number of covariates that can be adjusted for will be limited by the sample size. We chose to use mixed models versus GEE (generalized estimating equations) to avoid bias due to unequal cluster sizes or sample size.

More specifically, for hypothesis 3b(1) to compare the treatment arms on PCC behaviors in mental health care encounters we will use the MPCC, assessed only at time point 2. The independent variable will be the treatment group indicator. For hypothesis 3b(2) to examine whether relative to control the treatment group has greater functioning (subscales of the VR-36 and WHODAS), we will compare group means at time points 3 and 4 using a linear mixed model ANCOVA. The comparison at time point 3 will be primary and at time point 4,

secondary. For this hypothesis, after adjustment for baseline, there will be 2 repeated measures (time points 3 and 4) which will be assumed to be correlated (i.e. thru correlated error terms). However, contrasts will be specified in order to compare the groups at time point 3, separately from time point 4.

Aim 3, secondary and exploratory analyses. Secondary preliminary efficacy outcomes in the treatment group are (1) Veteran attrition from VA mental health care as compared to the control participants as established via chart review at TP3 and TP4 and (2) levels of Veteran self-assessment of clinical symptomology with the DASS-21, AUDIT, DAST 10, and PCL-5 at time points 1, 3, and 4. For (1) we will
determine the proportion of scheduled mental health care appointments that participants did not attend or canceled between TP1 and TP3 and TP3 and TP4, via chart review for the treatment and control groups. Proportions rather than raw counts will be analyzed to account for different patients having different numbers of scheduled appointments. If the number of different values for the proportions is few (say less than five), we will either define ordinal categories or dichotomize the proportions as there may be a lot zeros. We would then use a logit mixed model ANCOVA. If there are more than five unique values, but the distribution has substantial skew, we will again use an ordinal logit mixed model. Otherwise, if the distribution is close to symmetric we will use a linear mixed model ANCOVA. In either case we will use semi-parametric 'sandwich' standard errors known for their robustness to deviation from model assumptions. For (2), the self-assessment symptom measures will be analyzed to assess clinically significant change. Due to the heterogeneity of the inclusion
diagnoses this may involve forming subgroups based on baseline symptom severity, and therefore these analyses will be exploratory due to the small sample size. Additionally, we will form z-scores for each symptom measure and pool scores across symptom type as it is expected that all participants will have significant severity on at least one symptom measure. The DASS-21 and DAST 10 scores map onto five clinically meaningful levels and the AUDIT score maps onto four clinically meaningful levels. A mixed effects ordered logit model will be used to account for the ordinal levels of the response variable and will include random provider effect. A 10 point change on the PCL-5 has been established as clinically significant, hence, binary indicator variables will be constructed to indicate 10-point improvement (or not) at both TP3 and TP4. A mixed effects logistic regression model with random provider effect will be used to compare probability of 10-point improvement between the two groups.

In addition we will conduct exploratory analyses using data collected from the RCT examining whether Veteran perception of satisfaction with VA mental health care, therapeutic alliance, and personal agency differ between control and treatment conditions.

Mediation Analyses. As an example, the mediating effect of Personal Agency (from PAM) between the PCI intervention (PCI vs Control) and VR-36 Social Functioning subscale will be based on Sobel's test for an indirect effect. The first step is to test whether there is a total effect (path c-prime), i.e. a treatment group difference on the Social Functioning subscale at TP3. If there is a significant group difference on Social Functioning, then the second step will be to estimate both the effect of the PCI on Personal Agency (mediation path 'a') and the direct effect of Personal Agency on Social Functioning (mediation path b) when the treatment indicator is also in the model. Sobel's test tests the significance of the product a•b (indirect effect) by using a bootstrap 95% 'bias corrected' confidence interval. Same procedure will be used for other outcomes and mediators.

Moderator Analyses. Moderators will be tested by simply adding the main effect term and interaction term between the moderator and treatment group indicator to the main outcomes analysis model. Moderators must be assessed pre-intervention, hence at baseline. Evidence of moderation is provided if the interaction term is statistically significant. Moderators can be examined for MPCC (TP2), and the health and functioning outcomes (TP3).

Qualitative semi-structured interviews. Following the 3rd time point some participants (n=12) who attended all three intervention sessions will complete a qualitative semi-structured interview and some participants (n=5) who completed on or two intervention sessions will complete a qualitative semi-structured interview. Participants will be asked about their experience with the PCI, their thoughts about its overall utility, and their experiences participating via telehealth if their participation was impacted by the COVID-19 pandemic. This will include review of the format and content of the sessions, handouts, and educational materials. Interviews will begin with broad open questions about initial reactions, explore those thoroughly, and subsequently ask specific follow up questions to elicit information about each facet of the intervention and telehealth. After each interview the interviewer will append a field note documenting pertinent observations. Interviews will be in-person or by phone and recorded for verbatim transcription to facilitate coding.

Aim 3 analysis of semi-structured interviews. We will use qualitative RAP to analyze the semi-structured interviews. RAP is ideal for PAR studies with action-oriented goals: it uses team-based coding and focuses data analysis in order to answers to specific research questions.

*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:

Overall study results will be shared through publications. Per mandatory data sharing, final datasets will be maintained locally until enterprise-level resources become available. Final data sets will be made available to the public upon request. Specifically, complete person-level data will be provided as either a Limited Dataset or as a de-identified, anonymized dataset depending on the needs of the requester.

*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**
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

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

# 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:

1. Demographics Form - Veteran
2. Demographics Form - Provider
3. Consultation Care Measure
4. Perceived Involvement in Care Scale
5. Working Alliance Inventory-Client
6. Veterans RAND 36 Item Health Survey
7. World Health Organization Disability Assessment Schedule
8. Depression Anxiety Stress Scale
9. PTSD Checklist for DSM-5
10. Alcohol Use Disorders Identification Test-C
11. Drug Abuse Screening Test
12. Patient Activation Measure for Mental Health
13. Client Satisfaction Questionnaire
14. Patient Participation subscale of the Patient Empowerment Scale

For RCT participants

1. Demographics Form - Veteran
2. World Health Organization Disability Assessment Schedule 2.0
3. Veterans RAND 36 Item Health Survey
4. Alcohol Use Disorders Identification Test-C
5. Drug Abuse Screening Test
6. Depression Anxiety Stress Scale
7. PTSD Checklist for DSM-5
8. Mental Health Confidence Scale
9. Consultation Care Measure
10. Perceived Involvement in Care Scale
11. Patient Participation subscale of the Patient Empowerment Scale
12. Patient Activation Measure for Mental Health
13. Patient Activation Measure for Physical Health
14. Working Alliance Inventory-Client
15. Client Satisfaction Questionnaire
16. Technology Use Survey
17. Intervention Material Utilization (Omnis Salutis Utilization or Health and Wellness Utilization)
18. COVID Questionnaire

2 * Upload a copy of all questionnaires/surveys:

| Name | Created | Modified Date |
|---|---|---|
| COVID_questionnaire_05 18 2020.docx(0.01) | 5/18/2020 3:28 PM | 5/18/2020 3:28 PM |
| PAM PH(0.01) | 9/25/2019 5:13 PM | 9/25/2019 5:13 PM |
| Health and Wellness Utilization.docx(0.01) | 9/3/2019 1:21 PM | 9/3/2019 1:21 PM |
| Mental Health Confidence Scale.docx(0.01) | 9/3/2019 1:21 PM | 9/3/2019 1:21 PM |
| Omnis Salutis Utilization.docx(0.01) | 9/3/2019 1:21 PM | 9/3/2019 1:21 PM |
| Technology Use.docx(0.01) | 9/3/2019 1:21 PM | 9/3/2019 1:21 PM |
| WHODAS2.0_36itemsSELF.pdf(0.01) | 9/3/2019 1:21 PM | 9/3/2019 1:21 PM |
| AUDIT-C(0.02) | 10/20/2016 3:55 PM | 7/5/2019 1:44 PM |
| Patient Participation subscale of the Patient Empowerment Scale.docx(0.01) | 2/26/2019 2:09 PM | 2/26/2019 2:09 PM |
| Demographic Form Provider(0.01) | 6/26/2017 2:26 PM | 6/26/2017 2:26 PM |
| Demographic Form Veteran(0.02) | 10/20/2016 3:50 PM | 6/26/2017 2:26 PM |
| Client Satisfaction Questionnaire.docx(0.01) | 10/20/2016 3:57 PM | 10/20/2016 3:57 PM |
| PAM MH.pdf(0.01) | 10/20/2016 3:56 PM | 10/20/2016 3:56 PM |
| DAST-10 substance abuse measure.pdf(0.01) | 10/20/2016 3:55 PM | 10/20/2016 3:55 PM |
| PCL-5.pdf(0.01) | 10/20/2016 3:55 PM | 10/20/2016 3:55 PM |
| dass21.doc(0.01) | 10/20/2016 3:54 PM | 10/20/2016 3:54 PM |
| VR-36 FORM Version 1.0.doc(0.01) | 10/20/2016 3:52 PM | 10/20/2016 3:52 PM |
| MIRECC VA PCC WAI-C (42250 - Activated, Traditional).pdf(0.01) | 10/20/2016 3:51 PM | 10/20/2016 3:51 PM |

| Name | Created | Modified Date |
|---|---|---|
| MIRECC VA PCC PICS (52028 - Activated, Traditional).pdf(0.01) | 10/20/2016 3:51 PM | 10/20/2016 3:51 PM |
| Consultation Care Measure.docx(0.01) | 10/20/2016 3:51 PM | 10/20/2016 3:51 PM |

3 * What is the total length of time that each survey is expected to take?
Aim 1 surveys: 15 minutes
Aim 2 surveys (acceptability trial participants): 40 minutes per time point
Aim 3 surveys: up to 60 minutes per time point

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?

*ID: VIEW4E09460F5EC00*
*Name: v2_Surveys/Questionnaires*

HP-00063844 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 |
|---|---|---|
| PCC Aim 3 Qual interview guide.docx(0.02) | 5/1/2020 3:19 PM | 5/1/2020 3:39 PM |
| Acceptablility Individual Interview Script.docx(0.01) | 10/20/2016 4:11 PM | 10/20/2016 4:11 PM |

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

One hour

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

The interviews will be audio recorded by a member of the research staff and transcribed by a professional transcriptionist.

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: VIEW4E0947A633C00*
*Name: v2_Interviews*

HP-00063844

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 |
|---|---|---|
| Focus Group Script.docx(0.01) | 10/20/2016 4:13 PM | 10/20/2016 4:13 PM |

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

90 minutes

4 * How will the data be recorded?

Detailed notes will be taken by research staff.

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-00063844

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):

- [ ] 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)

Aim 1 = We audio recorded the participant-provider encounters for the purpose of capturing Veteran and provider PCC behaviors in mental health care encounters.

Aim 2 (acceptability trial participants only) & Aim 3 = We will be audio recording the qualitative interviews in order to capture main themes and understand the perspective of Veterans. We are also audio recording the individual sessions in order to provide feedback and train/supervise study staff on the intervention. After the individual sessions are complete the veteran will decide if they would like to participate in an optional one-time audio recording of one of their regularly scheduled mental health appointments to see if the study had an impact on their behavior.

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 recordings will not be labeled with any identifying information. They will be stored electronically, in a restricted access folder (accessible only to study staff) behind the VA firewall.

Audio recordings of encounters and 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 encounters and interviews.

Audio recording of individual sessions will be protected in the same manner listed above. They are stored electronically in the same manner listed above.
- If meeting face-to-face with a veteran for their individual session(s) is not possible then a trained study interventionist may (1) transport a study audio recorder to capture the audio of any individual session(s) completed via telehealth visit or (2) utilize the VA's protocol for Recording in CAG using Audacity Application and will export the recording to a restricted access VA sharedrive. If the interventionist uses an audio recorder they will utilize their locked HIPAA bag to transport the recorder, to ensure its protection.
- If meeting face-to-face with a veteran for their regularly scheduled mental health care is not possible and the veteran has provided consent to record one of their regularly scheduled mental health care appointments, then the study team will approach the veteran's mental health care provider to ask if they are willing to utilize the VA's protocol for Recording in CAG using Audacity Application. If they agree then the study team will make arrangements with the clinician to receive the recording via a sharedrive and immediately export the recording to a restricted access VA sharedrive.

*ID: VIEW4E094C128C800*
*Name: v2_Audio or Video Recording / Photographs*

**HP-00063844**

Behavioral Intervention_V2

# Behavioral Intervention

**You indicated that this study involves psychosocial or behavioral interventions.**

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

Aim 3
Treatment condition. We anticipate that the person-centered intervention (PCI) will be comprised of three, one-hour sessions offered over three to six weeks, scheduled at the participants' preference. Sessions will be one-on-one with the interventionist. The PCI sessions will be offered in a private room in the same buildings that VA mental health services are located in, on the two respective VAMHCS campuses OR will be offered via VA Video Connect, the VA's telehealth program which uses encryption to ensure a secure and private session, OR phone.

Control condition. The control condition will be an educational health and wellness intervention for stress related disorders that will match the experimental condition for time and attention. The control condition will be three, one hour, individual sessions covering the symptom cycle, managing stress, and identifying social supports. The interventionist will be a non-blinded member of the research team such as the
PI or coordinator. The control sessions will be offered in a private room in the same buildings that VA mental health services are located in, on the two respective VAMHCS campuses OR will be offered via VA Video Connect, the VA's telehealth program which uses encryption to ensure a secure and private session, OR phone.

*ID: VIEW4E0BC12A9F800*
*Name: v2_Behavioral Interventions*

HP-00063844

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)
- [x] **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*

# 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.

The following information will be collected from VA medical records: 1) Veteran name 2) Veteran address 3) period of military service 4) mental health/substance use diagnoses 5) initial date of mental health and/or alcohol/drug abuse treatment service use 6) last date of mental health and/or alcohol/drug abuse treatment service use.

Near the end of study participation, Veteran service use data will be collected for the period of time the Veteran was enrolled in the study. This will include number of mental health, physical health, and Whole Health appointments and appointment dates.

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-00063844

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-00063844

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

NCT02943408

*ID: VIEW4E093BF1D0800*
*Name: v2_Clinical Trial Registration Information*

HP-00063844 Participant Selection_V2

# 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.***
4000

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:
171

Worldwide - the number being enrolled total at all sites (including local enrollment):
171

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.:

*ID: VIEW4E0E519C1D000*
*Name: v2_Participant Selection*

HP-00063844

Vulnerable Populations_V2

# 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:

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-00063844 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 |
|---|---|---|
| Aim 3 Provider Eligibility Checklist(0.01) | 2/13/2019 4:45 PM | 2/13/2019 4:45 PM |
| Redline Aim 3 Veteran Eligibility Checklist 2.13.19(0.01) | 2/13/2019 4:44 PM | 2/13/2019 4:44 PM |
| Aim 3 Veteran Eligibility Checklist 2.13.19(0.03) | 11/17/2016 5:42 PM | 2/13/2019 4:44 PM |
| Aim 2 Acceptability Trial Participants(0.01) | 2/13/2019 4:40 PM | 2/13/2019 4:40 PM |
| Aim 2 Veteran Eligibility(0.02) | 11/17/2016 5:42 PM | 5/14/2018 4:07 PM |
| Aim 1 Veteran Eligibility Checklist track changes 9.28.17(0.01) | 9/28/2017 1:55 PM | 9/28/2017 1:55 PM |
| Aim 1 Vet Eligibility Checklist clean 9.28.17(0.01) | 9/28/2017 1:54 PM | 9/28/2017 1:54 PM |
| Aim 1 Provider Eligibility Checklist.docx(0.01) | 6/22/2017 12:00 PM | 6/22/2017 12:00 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-00063844_16 v2-13-2019-1550094370069(0.01)

*ID: VIEW4E0E5185F9000*
*Name: v2_Eligibility*

HP-00063844 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.):

Recruitment will take place at mental health clinics/programs within the VA Maryland Health Care System (VAMHCS). Potential VA 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, (5) self-referral via IRB approved announcements in the MIRECC newsletter, which is generated on a quarterly basis.

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

1. Email script for potential participants
Subject: research study eligibility
Hello,

I am on a research team that studies mental illness at the VA Maryland Health Care System. Currently, we are conducting a research study about ways to improve VA mental health care.

We would like to let you know that we believe you may be eligible for one of our studies. Your participation is entirely voluntary. If you do not want to participate, you will receive the same quality of care currently available to you. If you agree to participate, you will be reimbursed for your time and effort.

If you would like more information about this study, please respond to this email with YES OR call [staff] at XXX-XXX-XXXX.

If you do not want us to contact you, please respond to this email with NO.

If you do not respond we will contact you by phone to follow-up on this letter.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

2. Email script for potential participants who ask for more information via email
Subject: research study eligibility
Hello,
Per your request, here is information on the VA research study you are eligible for.
The study involves several types of appointments which take 6 hours of time split over multiple remote visits. We are currently conducting all visits over the phone and through encrypted, secure video chatting. To complete these appointments, you will need a computer/tablet with a microphone and camera or a smart phone. In the first appointment we would complete the informed consent paperwork for this study and have you complete a few questionnaires (1-1.5 hours).
You would then be matched with a study interventionist who will call you to schedule your individual meetings. You would meet three times for individual educational meetings where you will learn about patient-centered health care. These meetings can be scheduled during times that are convenient for you and would take about 1 hour per session. All visits with study interventionists will be conducted through encrypted, secure, telehealth video conferencing.
Approximately three and six months after the individual sessions are done you will complete study questionnaires. These would take about 45 minutes each. Each of the four times you complete questionnaires you will be compensated $50 for a total of $200 for your time. This payment will arrive in the form of an emailed gift card to Safeway or a check in the mail.
If you are interested in hearing more specifics, please respond with a good time to call you or call [VA staff] at XXX-XXX-XXXX. If you are no longer interested, please respond to this email with NO.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!

3. Email script for potential participants who have expressed interest in study participation
Subject: research study eligibility
Hello,

As you requested, we're following up about your interest in participating in a VA research study.
If you would like to schedule a time to meet with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

4. Email script for consent reminder with docs attached (encrypted email)

*The below message will be sent via encrypted email*

Subject: appointment materials

Hello,
We're following up as discussed about your initial appointment for the study. As requested, attached are blank electronic copies of the paperwork we will be discussing during that appointment. Our call is scheduled for [day], [date] at [time]. Research staff will call you at your preferred number. Please contact the research study team at XXX-XXX-XXXX if you have any questions prior to our phone call or if you need to reschedule.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

Omnis Salutis Study Team

Scripts for Enrolled Participants

5. Email script for study appointment reminder
Subject: appointment reminder
Reminder: You have a visit on DATE at TIME. Please call XXX-XXX-XXXX if you need to reschedule or have questions.
- If your appointment is by phone a member of the study team will call you at the specified date and time. You can call XXX-XXX-XXXX to confirm the telephone number they will call you at or from.

- If your appointment is by telehealth you can consult the attached instructions for using VA telehealth.
- If your appointment is in person and you would like to confirm the exact location, please contact XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

6. Email script for study appointment materials
Subject: appointment materials

Hello,

Attached are materials for an upcoming appointment. Please have them visible to you during your appointment. You do not need to complete these materials before the appointment. These materials do not contain any personal health or identifying information.

Please call XXX-XXX-XXXX if you need to reschedule or have questions. We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

7. Email script for electronic copies of intervention materials
Subject: blank materials
Hello,

As you requested, attached are blank electronic copies of the materials we discussed. These materials do not contain any personal health or identifying information.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

8. Email script for participant payments
Subject: payment
Hello,

As we discussed, attached are two $25 gift cards, for a total of $50. If you have any questions please call XXX-XXX-XXXX.

We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.

Thank you and have a great day!

9. Email script for participants re: scheduling appointment
Subject: research study follow up
Hello,
We're following up about your participation in a VA research study. It's time to schedule your next assessment. If you would like to schedule a time to meet with a study team member you can email us at OmnisSalutis@va.gov or contact us at XXX-XXX-XXXX.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!
10. Signature for sign-off
Email is not secure. Please do not reply back to this message with any personal information or personal health information.

If you are having thoughts of harming yourself, please call the Veterans Crisis Line at 1-800-273-8255.

* Confidentiality Notice *
This electronic message may contain confidential and legally protected information, intended only for the use of the individual or entity named in the message header. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of this electronic message and/or any attachments is strictly prohibited. If you have received this electronic message in error, please notify the sender immediately to arrange for your electronic email address to be removed from the sender's personal address book and/or distribution list.

******
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.

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

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

If approached for consent, the recruiter will assess competency to understand and sign the consent form by asking the individual a set of IRB approved questions (See attached evaluation to sign consent questions in Additional Documents). If the individual is unable to answer the questions correctly the RA will review aspects of the study that the individual did not understand. The RA will then ask the questions a second time. If the individual cannot answer them a second time they will be judged not competent to give consent, he or she will not be included in the study. Individuals 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.

**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 |
|---|---|---|
| Email scripts full(0.03) | 4/7/2020 2:04 PM | 1/13/2021 11:39 AM |
| Telehealth Considerations for Veterans 3.24.2020.docx(0.01) | 3/28/2020 10:49 AM | 3/28/2020 10:49 AM |
| Rec Letter for email 03 28 2020.doc(0.01) | 3/28/2020 10:48 AM | 3/28/2020 10:48 AM |
| Recruitment Email(0.01) | 2/19/2020 1:28 PM | 2/19/2020 1:28 PM |
| Recruitment letter w new letterhead(0.02) | 10/21/2016 10:59 AM | 3/15/2018 3:09 PM |
| recruitment card.docx(0.01) | 2/21/2017 1:21 PM | 2/21/2017 1:21 PM |

*ID: VIEW4E0BCAA0A6C00*
*Name: v2_Recruitment*

**HP-00063844** 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):

Text for paper flyers:

We are looking for
Veterans who served since 2001
who have been diagnosed with
PTSD, Depression, Anxiety, or a Substance Use Disorder

You will be paid up to $125 for participating in an Expert Advisory Panel .

Research will be conducted at the Baltimore VA.

Please call
[research staff name] at
410-637-XXXX
to see if you are eligible.

OR

We are looking for
Veterans who served since 2001
who have been diagnosed with
PTSD, Depression, Anxiety, or a Substance Use Disorder

You will be paid $25 for participating in a one-time focus group.

Research will be conducted at the Baltimore VA/ Perry Point VA.

Please call
[research staff name] at
410-637-XXXX
to see if you are eligible.

OR

Veteran receiving mental health services?
We are looking for Veterans who served after 2001 (age 18 and older) who have been diagnosed with PTSD, Depression, Anxiety, or a Substance Use Disorder for a research study about person-centered mental health care.

You will be paid for your participation.

Research will be conducted at the Baltimore VA/ Perry Point VA.

Please call [research staff name] at 410-637-XXXX to see if you are eligible.
Grab a number below and call us for more details!
VA Person Centered Care

OR

We are looking for
Veterans who served since 2001
who have been diagnosed with
PTSD, Depression, Anxiety, or a Substance Use Disorder
and are receiving
VA mental health care.

You will be paid $50 for participating in a research study.

Research will be conducted at the Baltimore VA/ Perry Point VA.

Please call
[research staff name]
at 410-637-XXXX

to see if you are eligible.

Text for electronic MIRECC newsletter/ MIRECC Currently Recruiting Studies website:

VA Person Centered Care
Veterans who served after 2001 who have been diagnosed with PTSD, Depression, Anxiety, Substance Use Disorder or other mental health disorders are invited to participate in a research study about person-centered mental health care.

You will be paid for your participation. Research will be conducted at the Baltimore and Perry Point VA.

Please call [research staff name] at 410-637-XXXX to see if you are eligible.

**1.3** * Upload advertisement(s) here:

| Name | Created | Modified Date |
|---|---|---|
| PPVA Flyer 7.5.2019(0.02) | 11/2/2017 2:55 PM | 7/5/2019 10:46 AM |
| BTVA Flyer 7.5.2019(0.02) | 11/2/2017 2:54 PM | 7/5/2019 10:44 AM |
| Aim 2 Perry Point Focus Group Flyer(0.01) | 5/8/2018 9:01 AM | 5/8/2018 9:01 AM |
| Aim 2 Baltimore Focus Group Flyer(0.01) | 5/8/2018 9:01 AM | 5/8/2018 9:01 AM |
| Aim 2 EAP Flyer(0.01) | 5/8/2018 9:00 AM | 5/8/2018 9:00 AM |
| Online recruitment blurb.docx(0.01) | 9/19/2017 12:17 PM | 9/19/2017 12:17 PM |

*ID: VIEW4E0BCE82B8C00*
*Name: v2_Advertising Detail*

HP-00063844

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:

Risks for Aim 1, 2, and 3
(1) Some participants may feel embarrassed or uncomfortable 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) Distress During Assessments (small likelihood, low degree of seriousness). Before consent and before and during each data collection, participants are informed that they are free to decline to answer any interview question(s) or to discontinue the interview at any time. If participants feel uncomfortable or fatigued, or seem so to the RA, they are encouraged to take a break and continue again later, or to stop the interview. In our research with people with mental health disorders over the past several years, few research participants have expressed distress from participating in the assessments and interviews. Nonetheless, all RAs have been trained to stop the interview 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.
(3) 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. Statistical analyses will be based on group data; no individual data will be reported. There is a slight risk of a confidentiality breach related to data collected for research purposes from participant interviews 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 interview assessment 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 Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201) or the VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD). 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 Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201) or the VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD). Consent forms which contain participants' names are kept in a locked cabinet in a locked office that is located in the Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201) or the VA Maryland Health Care System, MIRECC suite (209 W. Fayette Street, Baltimore, MD). Electronic data are kept on a password protected computer server, of which the passwords are only known to the study team members. Electronic research data are backed up regularly. 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.

Risks for Aims 1 and 3 and Aim 2, focus group and acceptability trial activities
(4) 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).

*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:
Participation in this study may provide no direct benefits to participants. However, participants may identify clearer goals for mental health treatment and learn how to effectively communicate those goals to providers and members of their social support networks.

2 * Describe the importance of the knowledge expected to result from the study:
This research will contribute to our understanding of how Veteran-focused person-centered care interventions might be used in health behavior change efforts for people with mental health 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, and potential loss of confidentiality. These risks are outweighed by the potential benefits of better understanding how Veteran-focused person-centered care interventions might be used in health behavior change efforts for people with mental health disorders. This understanding could underlie the development of new strategies to use as part of Veteran-focused person-centered care treatments for people with mental health disorders.

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.
Participation in this study is voluntary. The alternative is not to participate.

*ID: VIEW4E1B5251B0400*
*Name: v2_Potential Benefits and Alternatives*

# 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:

Veteran Participants will be withdrawn without their agreement under the following circumstances:
1) They have a serious reaction 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.

These circumstances have been outlined in the VA mandated 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*

# 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 training to protect the privacy of research participants. We meet with participants in private rooms with closed doors at the VAMHCS.

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:
Participants will receive research information in a private room with the door closed within the VA Maryland Health Care System (VAMHCS).

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-00063844

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.)

Documents for this study include:
1. Documents with identifiable information: Informed Consent Forms (ICF's), HIPAA Authorization forms, Subject locator forms, Evaluation to sign inform consent form. 2. Coded data: (2a) hard copies of assessment forms, (2b) coded electronic data 3. Videotapes/DVDs/Electronic Audio recordings
(1) Documents with identifiable information
All documents with identifiable information which contains participants' names but not their project ID number are collected at the VA and 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). 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).

(2) All data will be randomly 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 on the network drives BAL_MIRECC_Share or VHABALHackS$. Access to the link file will be limited to only study staff listed on this protocol.

(2a) Hard copies of assessment forms will be stored at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201) or the Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201).

(2b) Coded electronic data

Data capture and management of high quality data are key responsibilities of the Clinical and Translational Research Informatics Center (CTRIC) team. 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) Videotapes/DVDs/Electronic Audio 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 and DVD's of 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, 7th floor, Room 733, Baltimore, MD 21201). Any 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 on the network drives BAL_MIRECC_Share or VHABALHackS$. All audio/video recordings will be identified by codes only, and will not contain participants' names. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall on the network drives BAL_MIRECC_Share or VHABALHackS$.

3 * How will such data be secured?

(1) Documents with identifiable information

All documents with identifiable information which contains participants' names but not their project ID number 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). The file that links participant names to their project ID number will be stored behind the VA Firewall on the network drives BAL_MIRECC_Share or VHABALHackS$. 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).

(2) Coded data

(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, 7th floor, Room 733, Baltimore, MD 21201). Access to hard copies of coded research assessments 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 by transferring paper copies back to the VA by hand in a locked bag, and storing electronic data on a CD.

(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) Videotapes/DVDs/Electronic audio recordings

All video/audio recordings will be stored in a locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201). Videotapes/DVDs will be identified by codes only. Electronic audio recordings will be stored electronically behind the VA firewall on the network drives BAL_MIRECC_Share or VHABALHackS$.

**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. The data collected for this study will be used for research purposes only. Audio recordings of encounters and 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?

**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-00063844

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-00063844

Monitoring Plan - Individual_V2

# Monitoring Plan - Individual

**You indicated that the monitoring will be done by an Individual.**

1 * Identify the individual who will be performing the safety monitoring:
Samantha Hack

2 * Describe this individual's role in relation to the protocol:
Principal Investigator

3 * What data will be reviewed?

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

3.1 If Other, specify:
The Principal Investigator/Protocol Safety Monitor will maintain ongoing internal records regarding progress with study accrual, all study adverse events, compliance with eligibility criteria, participant adherence to study requirements, accuracy and completeness of data, and the findings of data checks and audits performed as a part of the VA Maryland Health Care System's study protocol standard procedures. These records will be made available to the IRB or other regulatory agencies upon request.

4 * What will be the frequency of the review?

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

4.1 If Other, specify:

5 * Safety monitoring results will be reported to:

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

5.1 If Other, specify:

*ID: VIEW4E1B026A2A400*
*Name: v2_Monitoring Plan - Individual*

HP-00063844

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) | 10/21/2016 3:17 PM | 10/21/2016 3:17 PM |

*ID: VIEW4E1B629EEC000*
*Name: v2_Compensation for Research-Related Injury*

HP-00063844

Payment to Participants_V2

# 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-00063844

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.***

$50/$25/$60/$125/up to $200/up to $250

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?

Because participants can only participate in one Aim/subsection of the study over the course of the whole study, the most one participant could receive is $125. Here is the timing and distribution of each aim/subsection.

Aim 1: one time payment of $50 following the research interview
Aim 2a: one time payment of $25 following focus group participation.
Aim 2b: payment of $20 following baseline research interview and $40 following post research interview and qualitative interview participation.
Aim 2c: Five payments of $25 each following each Expert Advisory Panel meeting.

Aim 3: Four payments of $50 each following each research interview (up to $200) and the potential for additional $50 if selected for qualitative interview participation ($250 total if selected for additional qualitative interview). Please note: for RCT participants who have completed some of their assessments prior to this study modification (anyone already enrolled) they will receive the increased amount of $50 for any remaining, future assessments they complete as part of the study

Participants will be paid upon receipt of completed data. Research staff will initiate payment via the agent cashier (if using VA voucher) or via electronic gift card depending on which method is preferred by the participant. If a participant selects the gift card option, research staff will send their electronic gift card via email using approved email script.

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.

*ID: VIEW4E1C54A6ACC00*
*Name: v2_Payment Detail*

HP-00063844 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*

HP-00063844

Protected Health Information_V2

# 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
- [x] **Email addresses**
- [x] **Social Security numbers**
- [x] **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, phone numbers and emails 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-00063844

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 for the period of time, starting March 17, 2020, that the VA Office of Research & Development prohibits in-person research encounters.

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.

This waiver of HIPAA Authorization is for information related to drug abuse and alcohol abuse. The purpose of the collection of this data is to conduct scientific research. No personnel involved in the study may identify, directly or indirectly, and individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

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.

In addition, without a temporary waiver of documentation of written HIPAA consent for the period of time, starting March 17, 2020, that the VA Office of Research & Development prohibits in-person research encounters, new participant enrollment would have to be halted.

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. This study has no study activities that must be conducted in person except for signing Informed Consent Forms and HIPAA Consents. Therefore we are requesting a permanent Waiver of Documentation of Consents to avoid undue risk to participants and research staff.

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:

Research study staff will halt in-person visits, beginning March 2020, due to COVID-19 precautions. Research staff will email or mail potential Veteran participants a copy of the informed consent form and then meet with the potential Veteran participants by phone or VA Virtual Care Manager (telehealth) in order to complete the informed consent process. 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, verbal 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.

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. Staff will ask participants if they have any questions once the document has been read and verbally confirm that the Veteran participant consents.

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 recruitment 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.

Once the national research restriction has been lifted by VA ORD the research study will immediately return to the previously approved consent protocol.

***

Written informed consent will be secured from study participants in Aim 1, Aim 2 acceptability trial participants, and Aim 3 participants enrolled prior to March 2020. During Aim 2, oral consent will be obtained from expert panelists and focus group members. An informational sheet outlining the basic elements of consent will be provided to all panelists prior to their participation in an EAP or focus group meeting.

Our research staff are carefully trained on obtaining consent from participants with serious mental illness and supervised by senior staff members.

Potential Veteran participants will be provided with 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, 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. 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. Staff will ask participants if they have any questions once the document has been read, 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 and d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

For potential provider participants in aims 1 and 3, consent forms will be emailed to them to review study information. A member of the study team will then meet with the providers individually to complete the informed consent process including a review of the information in the consent forms and to answer any questions they may have. Provider participants will be given a Notice of Privacy Practices (NOPP) form and an NOPP acknowledgement to sign. This form will be stored in their consent file.

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:
Veteran 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*

HP-00063844

Waiver of Documentation of Consent_V2

# 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:

A waiver of documentation of consent is being requested for Aim 2 Expert Advisory Panel (EAP) participants and Focus Group participants because no PHI will be collected from these participants.There will be no audio or video recording of these procedures. We will not collect any assessment data or additional information from these participants aside from their personal opinions during the panel or focus group discussion which will be noted by research staff notes of the meeting.

In addition, a temporary waiver of documentation of written consent is being requested for the period of time, starting March 17, 2020, that the VA Office of Research & Development prohibits in-person research encounters.

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. This study has no study activities that must be conducted in person except for signing Informed Consent Forms and HIPAA Consents. Therefore we are requesting a permanent Waiver of Documentation of Consents to avoid undue risk to 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:
This request for waiver of informed consent is 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.

In addition, a temporary waiver of documentation of written consent is being requested for the period of time, starting March 17, 2020, that the VA Office of Research & Development prohibits in-person research encounters. While the research study is no more than minimal risk, traveling to and participating in in-person consent procedures is more than minimal risk and should be avoided.

On July 31, 2020 VA Office of Research & Development lifted the administrative hold on in-person research if studies can demonstrate sufficient safety procedures and significant need to hold in-person research encounters. Therefore we request a permanent waiver of documentation of consent as this study continues to be minimal risk but travel and presence in VA facilities for in-person consent procedures is more than minimal risk and should be avoided.

2 * Explain why a waiver or alteration of the consent process would not adversely affect the rights and welfare of the subjects:
This 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 Waiver of Documentation of Consent, study participants 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:
This 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 addition, a temporary waiver of documentation of written consent is being requested for the period of time, starting March 17, 2020, that the VA Office of Research & Development prohibits in-person research encounters. If no waiver is granted, recruitment will cease.

On July 31, 2020 VA Office of Research & Development lifted the administrative hold on in-person research if studies can demonstrate sufficient safety procedures and significant need to hold in-person research encounters. Therefore we request a permanent waiver of documentation of consent as this study continues to be minimal risk but travel and presence in VA facilities for in-person consent procedures is more than minimal risk and should be avoided. If written consent is required it is unlikely VA would feel this meets the threshold for necessary in-person encounters and enrollment would have to cease.

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 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 |
|---|---|---|
| Aim 3 Veteran ICF Redline Version 3.26.2020(0.06) | 3/15/2017 10:18 AM | 3/26/2020 9:11 AM |
| Aim 3 Veteran ICF Clean Version 3.26.2020(0.07) | 5/8/2018 9:31 AM | 3/26/2020 9:10 AM |
| Aim 3 Provider ICF Redline Version(0.02) | 3/16/2017 11:31 AM | 5/8/2018 9:21 AM |
| Aim 3 Provider ICF Clean Version(0.02) | 5/8/2018 9:32 AM | 5/31/2018 1:21 PM |
| Veteran ICF Addendum (Aim 2 Acceptability Trial, RCT)(0.01) | 2/13/2019 4:47 PM | 2/13/2019 4:47 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 |
|---|---|---|
| Aim 2 Vet Acceptability Trial ICF 3.26.2019(0.06) | 2/21/2017 1:22 PM | 3/29/2019 9:53 AM |
| Aim 2 Acceptability Trial ICF Redline 3.26.2019(0.02) | 2/27/2019 8:18 AM | 3/26/2019 8:29 AM |
| ICF Aim 1 Veteran 1.23.2018(0.01) | 1/23/2018 1:14 PM | 1/23/2018 1:14 PM |
| ICF Aim 1 Provider 1.23.2018(0.01) | 1/23/2018 1:14 PM | 1/23/2018 1:14 PM |

2 Upload any HIPAA authorization forms here:

| | | |
|---|---|---|
| VHA HIPAA Form Aim 2 Acceptability Trial(0.04) | 11/14/2016 12:59 PM | 2/27/2019 8:19 AM |
| VHA HIPAA Form Aim 3(0.02) | 12/13/2017 11:32 AM | 2/27/2019 8:19 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*?

Recent Veterans are at significant risk of experiencing stress-related mental health disorders such as PTSD, depression, anxiety, and substance use disorders, and subsequently, difficulties in health, home, purpose, and community functioning. Research indicates that recent Veterans in VA treatment for stress-related mental health disorders have unacceptably high dropout rates and that such Veterans would prefer personalized mental health care that supports their functional recovery. Simultaneously, the VA has begun a system-wide transformation with the goal of moving from disease centered care to personalized, proactive, PCC. Based on my preliminary research (presented in section 2), Veterans have the desire to be actively involved in their mental health care but do not typically achieve the level of participation they want. This is in keeping with research that interventions that change patient behaviors and engagement are most effective at improving the patient centeredness of care and functional outcomes.

While the VA has introduced provider-focused PCC training interventions, no Veteran-targeted PCC interventions exist to prepare Veterans to engage collaboratively with VA providers. We lack both knowledge about what barriers are impeding Veteran engagement in PCC and an intervention to increase Veteran engagement in mental health care and support recent Veterans' functional recovery from stress-related mental health disorders. This proposal will directly address this knowledge gap first by gathering foundational knowledge about Veteran and provider PCC behaviors in VA mental health care. I will accomplish this by coding and analyzing recordings of provider-recent Veteran mental health care encounters (n=35) to identify behaviors that facilitate and inhibit PCC in VA mental health care, in order to develop a targeted intervention. Second, I will partner with Veterans, VA providers, and VA researchers to develop and pilot a brief, Veteran-targeted patient centered mental health intervention (patient centered intervention; PCI) led by a Veteran peer specialist to educate Veterans about PCC, help them identify their treatment goals, and catalyze their involvement in treatment planning. I will conduct a clinical demonstration (n=10) of the PCI to examine acceptability and further refine it and then a pilot RCT (n=48) to assess feasibility and preliminary efficacy. This PCI will support the expansion of VA PCC to mental health care settings, and VA PCC initiatives generally.

As outlined in my career plan, I aspire to develop effective and empowering interventions to enhance the functional recovery of Veterans with mental health disorders. Understanding and expanding VA patient centered mental health care for recent Veterans with stress-related mental health disorders is a core component and logical starting point for these efforts. Developing a brief, Veteran-targeted, PCI is the critical next step in building my program of research and intervention development. Results from this research will lay the groundwork for my long-term career goal of becoming a VA subject matter expert in patient centered mental health care. In this role, I aim to develop interventions that support Veteran activation and coequal collaboration between Veterans and providers in mental health care planning and treatment, in the service of improving Veteran functioning. Furthermore, I will explore the use of PCC interventions as a means of improving vulnerable populations' mental health care outcomes and reducing disparities in VA mental health care. In the latter half of the proposed award period I will prepare and submit an Investigator-Initiated Research proposal (IIR, e.g. VA Merit) to test the brief, Veteran-targeted, PCI in a large and heterogeneous sample of Veterans with stress-related mental health disorders. Informed by the findings from this CDA, that project will enable my larger goal of a series of mixed-methods studies designed to improve Veterans' functional rehabilitation outcomes by refining interventions to target key mechanisms of change, expanding eligible mental health disorders for intervention, and developing targeted modifications for populations experiencing treatment disparities.

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.):

Clinicians to Veterans

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:

Part of the purpose of this study is to understand patient centered care communication in VA mental health care encounters and toward that end we will record VA mental health care encounters. Therefore we must obtain permission from both members of the therapeutic dyad (provider and consumer) in order to record and analyze communication patterns.

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.
---
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]

*ID: VIEW4E1C7A737E800*
*Name: v2_Use of Non-Veterans*

HP-00063844

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-00063844

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-00063844

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*

**HP-00063844**

Summary of Required Reviews_V2

# 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** |
|---|---|
| School of Social Work | Pending |

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

**HP-00063844**

Additional Documents_V2

# Additional Documents

1

Upload all additional documents here:

| Name | Created | Modified Date |
|---|---|---|
| COVID risk statement(0.01) | 11/4/2021 9:16 AM | 11/4/2021 9:16 AM |
| Email Scripts(0.03) | 2/19/2020 1:29 PM | 11/4/2021 9:11 AM |
| Lillian Hammer Privacy Security(0.01) | 6/19/2019 3:00 PM | 6/19/2019 3:00 PM |
| Lillian Hammer CITI(0.01) | 6/19/2019 2:45 PM | 6/19/2019 2:45 PM |
| Lillian Hammer HIPAA(0.01) | 6/19/2019 2:44 PM | 6/19/2019 2:44 PM |
| VA Privacy and HIPAA Tracy Robertson(0.01) | 2/27/2019 12:23 PM | 2/27/2019 12:23 PM |
| VA Privacy and Info Security Tracy Robertson(0.01) | 2/27/2019 12:23 PM | 2/27/2019 12:23 PM |
| CITI Training Tracy Robertson(0.01) | 2/27/2019 12:23 PM | 2/27/2019 12:23 PM |
| Privacy and Info Security Howard Turner(0.01) | 2/27/2019 12:22 PM | 2/27/2019 12:22 PM |
| Privacy and HIPAA Howard Turner(0.01) | 2/27/2019 12:22 PM | 2/27/2019 12:22 PM |
| CITI Training Howard Turner(0.01) | 2/27/2019 12:22 PM | 2/27/2019 12:22 PM |
| CITI Training Peter Phalen(0.01) | 2/27/2019 12:21 PM | 2/27/2019 12:21 PM |
| VA Privacy and Info Security Training Peter Phalen(0.01) | 2/27/2019 12:21 PM | 2/27/2019 12:21 PM |
| Privacy and HIPAA Training Peter Phalen(0.01) | 2/27/2019 12:20 PM | 2/27/2019 12:20 PM |
| Expert Advisory Panel Information Sheet.docx(0.01) | 5/24/2018 3:03 PM | 5/24/2018 3:03 PM |
| Focus Group Information Sheet.docx(0.01) | 5/24/2018 3:03 PM | 5/24/2018 3:03 PM |
| ISO PO Checklist 1.23.2018(0.01) | 1/23/2018 1:02 PM | 1/23/2018 1:02 PM |
| VA NOPP Acknowledgement(0.01) | 4/17/2017 11:09 AM | 4/17/2017 11:09 AM |
| VA NOPP(0.01) | 4/17/2017 11:09 AM | 4/17/2017 11:09 AM |
| VA Human Subjects Protection CITI.pdf(0.01) | 2/27/2017 2:08 PM | 2/27/2017 2:08 PM |
| Full Grant Application(0.01) | 2/21/2017 12:04 PM | 2/21/2017 12:04 PM |
| ISO PO checklist-HP-00063844.pdf(0.01) | 1/26/2017 2:25 PM | 1/26/2017 2:25 PM |
| Subject Locator form.doc(0.01) | 11/17/2016 10:30 AM | 11/17/2016 10:30 AM |
| Evaluation to Sign Consent.doc(0.01) | 11/17/2016 10:30 AM | 11/17/2016 10:30 AM |

*ID: VIEW4E0962513A000*
*Name: v2_Additional Documents*

**HP-00063844**

Final Page of Application_V2

# 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** |
|---|---|
| School of Social Work | Pending |

**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-00063844

IRB - Add a Team Member

# Add a Team Member

1 * Select Team Member:
Alicia Lucksted

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:
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-00063844

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-00063844

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-00063844

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 Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member and peer support specialist. 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 very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00063844

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.

HP-00063844

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 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-00063844

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 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. She has been specially trained in how to work with individuals who have serious mental illness. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00063844

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 has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for several years. She has been specially trained in how to work with individuals who have serious mental illness. Additionally, she has already worked on numerous VA studies with Veterans at the VAMHCS. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00063844

IRB - Add a Team Member

# Add a Team Member

1 * Select Team Member:
Amy Drapalski

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:
Amy Drapalski has been working with the MIRECC for a number of years. 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-00063844

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 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-00063844

IRB - Add a Team Member

# Add a Team Member

1 * Select Team Member:
Melanie Bennett

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 Bennett has been a member of the faculty within the Center for Behavioral Treatment of Schizophrenia in the Department of Psychiatry and the VAMHCS for a number of years. She 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. Bennett has conducted or participated in research involving this population at the study sites where the proposed research will take place as well as other mental health centers across the region. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00063844

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 Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member and peer support specialist. 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 very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

HP-00063844

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 Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member. She has been specially trained in how to work with individuals who have mental illness. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.